California State Board of Pharmacy
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Licensing Committee Report

Ruth Conroy, PharmD, Chair
Clarence Hiura, PharmD, Member
Susan Ravnan, PharmD, Member
Robert Graul, RPh, Member

Minutes of the Licensing Committee Meeting held March 7, 2007 are provided near the back of this tab section as **Attachment A.**

A. Update of the Committee's Strategic Plan for 2007-08

ACTION REQUESTED: Amend and approve the committee's strategic plan for 2007-08 by adding two activities to objective 2.4 "Implement at least 25 changes to improve licensing decisions by June 30, 2011"; specifically, to add:

8. **Participate with California's Schools of Pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards.**
9. **Implement new test administration requirements for the CPJE.**

During the March 7, 2007 meeting, the committee reviewed the Licensing Committee's strategic plan but recommended no changes. Upon compilation of the minutes, staff recommends the above additions to the strategic plan for this committee so that the strategic plan tracks and reports major activities. If the board wishes to incorporate these changes, a motion and second will be needed.

Attachment 1 contains the committee's current strategic plan.

B. Request by Pacific University of Oregon to Receive Board Recognition for Purposes of Issuing California Intern Licenses

FOR ACTION: Recommend approval of Pacific University School of Pharmacy for purposes of issuing intern pharmacist licenses to its students.

Pacific University School of Pharmacy has requested that the Board of Pharmacy recognize its school of pharmacy for purposes of approving intern applications (see **Attachment 2**).

Current regulation, 16 CCR section 1719, states that a "recognized school of pharmacy" means a school accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education (ACPE).

Pacific University School of Pharmacy is in precandidate status, but is proceeding toward eligibility to candidate accreditation status.

According to the ACPE, its board of directors will make a decision on the status of Pacific University School of Pharmacy in June 2007 with information available to the general public in mid-July. A program that achieves candidate accreditation status can remain in this status from 2-4 years before advancing to full accreditation status. Historically, pharmacy programs that advance to candidate status do achieve full accreditation status, but ACPE cannot guarantee that any particular school will do so in the future.

C. **Request to Accept the Certification Examination of the Commission for Certification in Geriatric Pharmacy for Continuing Education Credit for Pharmacists**

COMMITTEE RECOMMENDATION: Direct the Commission for Certification in Geriatric Pharmacy to appear before the board to present information on this examination and certification process; after which the board will consider its options

At the December Licensing Committee Meeting, the committee briefly reviewed the materials from the Commission for Certification for Geriatric Pharmacy (CCGP), which offers a program for pharmacists to become "certified geriatric pharmacists." The commission requested (via a letter) that the board grant CE for pharmacists who become certified. Four states are now awarding CE for becoming certified. However, the Licensing Committee did not take action on this item because no one from the commission appeared at the meeting.

The executive director of the commission (which is located in Virginia) could not attend the March Licensing Committee meeting, but is planning to attend this April Board Meeting to make a presentation on this examination directly to the board.

Thereafter, the board can determine whether it wishes to move forward on the proposal or refer the matter back to the committee. If the board wishes to pursue this proposal, a regulation change may be needed.

Attachment 3 contains information about this examination provided to the board by the commission.

Background:

Pharmacists are required to earn 30 hours of approved CE every two years as a condition of license renewal. Currently pharmacists can earn CE:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR 1732.05).
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR 1732.2), or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR 1732.2).

Additionally, the board will award CE for:

- Attending one board meeting annually (6 hours of CE)
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings)
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 units)

Proposal:

The Commission for Certification in Geriatric Pharmacy (CCGP) offers a program for pharmacists to become Certified Geriatric Pharmacists. There are currently 1,300 certified geriatric pharmacists in the United States, Canada, Australia and other countries.

To become certified, the individual must pass a 3-hour, 150-question examination covering three major areas: Patient Specific, Disease Specific and Population Specific activities. The exam has been psychometrically validated by a firm specializing in such processes.

Four states, including Ohio and Washington, recognize CCGP's certification examination for continuing education credits.

If Licensing Committee recommends, and the board agrees, to award CE for the CCGP exam, staff will add a provision to the proposed regulation.

D. Proposed Regulations for Pharmacies that Compound Medication – Amendments to 16 California Code of Regulations Sections 1716.1 and 1716.2, and the Adoption of Sections 1735-1735.8

FOR INFORMATION:

At the January 2007 Board Meeting, the board moved to regulation hearing proposed regulations for pharmacies that compound medication, providing patient protections when they receive medication compounded by a pharmacy. These regulations were developed during 2004 while the board was convening its Work Group on Compounding with stakeholders and other regulatory agencies.

At the January Board Meeting, noting that some individuals may wish to comment on the regulations before they are formally noticed, the board also asked that those individuals with comments to provide these comments to the Licensing Committee by the end of February.

Comments were received immediately before the meeting from Dan Wills, joint comments from CPhA/Kaiser/and Dan Wills, and NACDs.

The comments are provided in **Attachment 4**. All comments but those of NACDs were also inserted into the draft regulations.

More work is needed on the proposed language before it is released for public comment. Before the next meeting of the Licensing Committee, staff will work on refining a new draft. At the next Licensing Committee Meeting, the committee can review the proposed regulation language and determine if it is ready to move to the board to release for the rulemaking.

Meanwhile in Washington DC, Senator Kennedy has introduced legislation that would restrict how pharmacies compound. A copy of this legislative proposal is provided in **Attachment 5**.

E. Proposals for Future Legislative Change

PROPOSAL 1:

FOR ACTION: Pursue Amendment of Sections 4200-4200.3 of the California Business and Professions Code regarding the statutory reference to what the board calls the California Pharmacist Jurisprudence Examination (CPJE) to more accurately reflect the statutorily established breath of the exam to: The California Pharmacist-Patient Communication and Jurisprudence Examination.

For several years, concern has been expressed that questions on the California Pharmacist Jurisprudence Examination are not exclusively law questions. The California Business and Professions Code section 4200.2 directs that the board's state examination provide an examination whereby:

(a) Examination items to demonstrate the candidate's proficiency in patient communication skills.

(b) Aspects of contemporary standards of practice for pharmacists in California, including, but not limited to, the provision of pharmacist care and the application of clinical knowledge to typical pharmacy practice situations that are not evaluated by the North American Pharmacy Licensure Examination.

The Licensing Committee recommends that a more reflective name for the examination is in order – there is absolutely no change being proposed in the required scope of the examination.

Staff recommends that the board retain the acronym CPJE for the new name, thus the proposal is to change the name of the examination to the California Pharmacist-Patient Communication and Jurisprudence Examination. **Attachment 6** contains the proposal language inserted into the Business and Profession Code.

PROPOSAL 2:
FOR ACTION: Recommend that the board approve the establishment of a state protocol under which pharmacists can administer vaccines. Amend section 4052(a)(9) to allow pharmacists to administer immunizations pursuant to the National Protocol for Vaccinations

At the March 7 Licensing Committee, Jeff Goad, PharmD, a professor at USC, provided information to the committee about a proposal to establish a statewide protocol under which pharmacists could administer immunizations if using the CDC's National Protocol for Vaccinations. If such a statutory modification is made, the board would need to develop regulations with specific protocols in them.

Dr. Goad stated that in 44 states, pharmacists can administer immunizations. In California, pharmacists can administer immunizations under a protocol with a physician. However, some physicians are reluctant to accept the liability for this action, even though the practice has wide support. Dr. Goad distributed information about pharmacy immunization protocols for a number of vaccines (**Attachment 7**).

Under the proposal, which is parallel to the state emergency contraception protocol under which pharmacists can provide emergency contraception, a pharmacist could provide immunizations if following the state protocol.

Discussion of those attending the meeting was very supportive.

A copy of the proposed statutory modification to Business and Professions Code section 4052 is in **Attachment 7**.

Board staff will undertake more work on this proposal, including working with the board's legal counsels.

F. Emergency Preparedness for California Pharmacy

INFORMATION ONLY:

One of the Governor's key initiatives is emergency preparedness. The board has an important role in this because the provision of pharmaceuticals, and who will provide them, will certainly be an important component in any emergency response.

At the October Board Meeting, the board amended and approved a general policy statement that outlines its expectations for how disaster response in California may proceed. This policy statement is on the board's Web site and was published in the January 2007 *The Script*.

For seven days in late February and early March, the state hosted a conference for state agencies to compile materials for disaster preparedness. Several inspectors from the board and Committee Chair Conroy attended part of this training.

- February 27-March 1: Surge Response
- March 5-6: Standards and Liability
- March 8-9: Reimbursement

Board Inspector Ralph Orlandella and Supervising Inspector Coyne have been asked to provide a short update on this training at this board meeting. Any materials developed as a result of this training that can be shared with the board will be provided in the future (none have been distributed to date). A brief overview of this training is provided in **Attachment 8**.

The board recognizes disaster preparedness and emergency response as key board initiatives. Over the coming months, the board will work with the Department of Health Services, the Office of Emergency Services and other agencies to continue to participant in developing procedures for emergency response. The goal is to assure that licensees and the public have better knowledge of what the board will require, and licensees will be comfortable volunteering to participate in emergency response and obtain training before a disaster occurs.

G. Request to Add the Exam for the Certification of Pharmacy Technicians as a Qualifying Method for Pharmacy Technician Registration

INFORMATION ONLY:

In California, individuals may become qualified for registration as pharmacy technicians by one of four means:

1. Possessing an associate's degree in pharmacy technology.
2. Completing a course of training specified by the board in regulations (accredited by ASHP, provided by the armed forces, or at least 240 hours of instruction covering specific topics).
3. Graduating from a school of pharmacy recognized by the board.
4. Being certified by the Pharmacy Technician Certification Board.

In September the Licensing Committee began a discussion regarding another pharmacy technician examination, the Exam for the Certification of Pharmacy Technicians (ExCPT). This exam has been developed by the Institute for the Certification of Pharmacy Technicians, and other states accept it as a qualifying route for technician registration.

In California, section 139 of the Business and Professions Code requires a periodic assessment of all licensure examinations used by a regulatory agency for job-relatedness. So before recommending action on this examination, the board should assure that it is job-related. Discussions are currently underway between the board and departmental staff on establishing a method to initiate a review of the ExCPT exam, as well as the PTCB.

To use the ExCPT exam as a qualifying method for pharmacy technician licensure, either a statutory or regulation amendment needs to be adopted. The board should not act to implement this exam until this review is completed.

There has been no action on this project since the October Board Meeting, when the board directed that a review of the ExCPT exam take place. Staff had planned to use a PhD psychometric expert from the DCA's Office of Examination Resources to assist the board in performing this review. However, the position has been vacant since September, and the department is having a difficult time with recruitment of such a professional.

However, during discussion of this examination at the Licensing Committee meeting, some in the audience thought that there is the need for evaluation of the training of technicians. Apparently both CPhA and CSHP are taking a look at the performance required of technicians, and whether additional qualifications are needed.

Dr. Ravnan stated that she believes that there needs to be more than just an examination component for pharmacy technicians – practical training is also important. The SCR 49 Medication Errors Report will include a statement for the need for well-trained technicians.

H. California Schools of Pharmacy Project to Identify and Test on the Professional Competencies that Should be Achieved by the End of Basic Intern Experience

The Board of Pharmacy voted to join in a project initiated by California's schools of pharmacy, who are working together with other stakeholders to evaluate the components of ACPE approved intern experience at both the basic (IPPE) and advanced (APPE) levels. The project is called the California Pharmacy IPPE/OSCE Initiative. The goal is to develop an alternative component to assessing intern experience. Dr. Ravnan is the board's appointee to this project, which also involved the board's executive officer and legislative coordinator. Three meetings have been held to date.

Three day-long meetings have taken place, and a list of competencies that students should achieve during the basic level of internship is being finalized. Next the schools hope to develop a performance-based exam (i.e., objective structured clinical exam, OSCE) to assess student achievement of these competencies.

Materials from the early meetings are provided in **Attachment 9.**

I. Competency Committee Report:

- *Test Administration Contract*

  The Office of Examination Resources within the Department of Consumer Affairs awarded a new contract with a vendor to provide computer based testing through a Request for Proposal (RFP) process. The board uses this contract to administer the CPJE, and most other agencies within the department that provide computer-based testing also use this contract.

  The new company is Psychological Services LLC (PSI), which is contracted to begin providing examinations on June 1, 2007.

  While there was a protest filed with the Office of Examination Resources, the contract was nevertheless awarded since the new agreement contained language to move forward with a winning vendor even if there should be a protest.

  Given that there will be a new vendor on June 1, there will be transition issues for those seeking to take the CPJE, and the timing is bad for June pharmacy school graduates. The board has developed materials to educate applicants about the new testing company. However, it is now six weeks before the new vendor takes over the testing procedures and the board does not have any information about how to apply to take the exam from the new vendor and what testing locations exist.

  Staff is working with California pharmacy schools to aid them in getting their graduates into the examination at Thompson Prometric sites if the students graduate prior to mid-May and are so interested.

  An informational fact sheet has been prepared (**Attachment 10**), and all CPJE-eligible candidates have been notified they need to schedule and take the examination with Thompson Prometric before June 1, 2007.

- *CPJE Pass Rate Summary*

  We currently are awaiting the pass-fail statistics for the CPJE from October 1, 2006 through March 31, 2007 from our examination vendor. We hope to be able to distribute them at the Board Meeting.

J. Meeting Summary:

A summary of the Licensing Committee Meeting of March 7, 2007 is provided in **Attachment A.**

Attachment 1

Licensing Committee Strategic Plan

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

Objective 2.1	Issue licenses within three working days of a completed application by June 30, 2011.
Measure:	Percentage of licenses issued within 3 work days
Tasks:	1. Review 100 percent of all applications within 7 work days of receipt. 2. Process 100 percent of all deficiency documents within 5 work days of receipt. 3. Make a licensing decision within 3 work days after all deficiencies are corrected. 4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements. • Pharmacists • Intern pharmacists • Pharmacy technicians • Foreign educated pharmacists (evaluations) • Pharmacies • Non-resident pharmacies • Wholesaler drug facilities • Veterinary food animal drug retailers • Exemptees (the non-pharmacists who may operate sites other than pharmacies) • Out-of-state distributors • Clinics • Hypodermic needle and syringe distributors 5. Withdraw applications of applicants not meeting board requirements or where the application has been abandoned. 6. Deny applications to those who do not meet California standards.
Objective 2.2	Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2005.
Measure:	Percentage of cashiered application and renewal fees within 2 working days
Tasks:	1. Cashier application fees. 2. Cashier renewal fees 3. Secure online renewal of licenses

Objective 2.3	Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2005.
Measure:	Percentage of licensing records changes within 5 working days
Tasks:	1. Make address and name changes. 2. Process discontinuance of businesses forms and related components. 3. Process changes in pharmacist-in-charge and designated representative-in-charge. 4. Process off-site storage applications. 5. Transfer of intern hours to other states
Objective 2.4	Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Measure:	Number of implemented changes
Tasks:	1. Determine why 26 states do not allow the use of a CA license as the basis for transfer a pharmacist license to that state. 2. Work with the University of California to evaluate the drug distribution system of its clinics and their appropriate licensure. 3. Work with the Department of Corrections on the licensure of pharmacies in prisons. 4. Work with local and state officials on emergency preparedness and planning for pandemic and disasters. Planning to include the storage and distribution of drugs to as sure patient access and safety. 5. Evaluate the need to issue a provisional license to pharmacy technician trainees. 6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians. 7. Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008. 8. Participate with the schools of pharmacy in reviewing basic level experiences required of intern pharmacists. 9. Implement new test administration requirements for the CPJE.
Objective 2.5	Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2011.
Measure:	Number of public policy initiatives evaluated
Tasks:	

Attachment 2

Request from Pacific University of Oregon to Receive Board Recognition for Purposes of Issuing California Intern Licenses

PACIFIC UNIVERSITY
1849
OREGON

School of Pharmacy
222 SE 8th Ave., Suite 451
Hillsboro, OR 97123
Phone (503) 352-7283 • Fax (503) 352-7270
Website: http://www.pacificu.edu/pharmd/

January 12, 2007

California State Board of Pharmacy
Virginia Herold, Interim Executive Officer
1625 N Market Blvd., N219
Sacramento, CA 95834

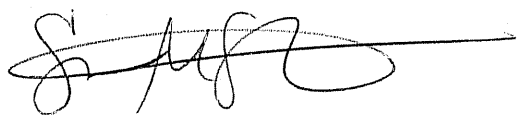
Dear Board of Pharmacy,

This letter formally requests recognition of the Pharm. D. Program of Pacific University School of Pharmacy by the Board of Pharmacy of the State of California.

Pacific University School of Pharmacy was granted Pre-Candidate status in June, 2006 and matriculated its inaugural class the following August. Our students undergo experiential training throughout their curriculum and it is expected that a number of them will undertake pharmacy practice rotations in diverse locales around the national beginning in June, 2007.

We look forward to hearing from you at your earliest possible convenience. Please do not hesitate to contact me with any questions.

Yours truly,



Susan M. Stein, M.S., R.Ph.
Assistant Dean for Clinical Programs and Student Development
Pacific University, School of Pharmacy
222 SE 8th Ave., Suite 451
Hillsboro, OR 97123
(503) 352-7285
steins@pacificu.edu

Attachment 3

Request of the Commission for Certification in Geriatric Pharmacy to Award CE for Pharmacists Who Become Certified Geriatric Pharmacists

September 5, 2006

Patricia F. Harris
California Board of Pharmacy
1625 N Market Boulevard, N219
Sacramento, CA 95834

Dear Ms. Harris:

I am writing to request that the California Board of Pharmacy consider recognition of our certification examination as at least one approved source for purposes of meeting the Pharmacy Board's current Continuing Education requirements.

At present, at least two states, Ohio and Washington, recognize CCGP's certification examination for continuing education credits. We are seeking similar recognition among the other state boards of pharmacy.

Our examination is 3 hours and is composed of 150 multiple choice questions addressing three major domains: Patient Specific, Disease Specific, and Population Specific activities. It has been structured according to currently excepted psychometric principles and is administered on our behalf by Applied Measurement Professionals (AMP), one of the major psychometric firms in the United States. The exam, itself, is based upon a detailed content outline that was produced from a Practice Analysis in 2003. I have enclosed a copy of our current Candidate Handbook. It provides an outline of that Content Map. The Candidate Handbook also provides a brief description of CCGP and sets forth the rules and policies for earning and maintaining certification.

Our certification is the only population specific specialty designation in the pharmacy profession and has been awarded to more than 1,300 board Certified Geriatric Pharmacists, in good standing who practice in the United States, Canada, Australia and other international locations. We believe that CCGP certification is tangible evidence that a board Certified Geriatric Pharmacist is uniquely qualified to provide pharmacy care to the frail and elderly. Furthermore, while the new Medicare Part D program is still in its infancy, we are beginning to see evidence that CCGP certification is becoming at least one criterion for selecting pharmacists for participation on Pharmacy and Therapeutics Committees and networks of providers used by Pharmacy Benefit Managers and Prescription Drug Plans to provide drug benefit services.

We would appreciate the Board's willingness to consider our request. Please feel free to visit our website www.ccgp.org for more information, including the ability to download our Candidate Handbook. If you have any questions, you can contact me by email at lhoxie@ccgp.org or by telephone at (703) 535-3038.

Sincerely,

Lance O. Hoxie
Executive Director

COMMISSION FOR CERTIFICATION IN GERIATRIC PHARMACY

1321 Duke Street • Alexandria, VA 22314
703.535.3038 • Fax 703.739.1500
www.ccgp.org • info@ccgp.org

Candidate Handbook • Candidate Handbook • Candidate Handbook

Certification Examination in Geriatric Pharmacy

Sponsored by
Commission for Certification in Geriatric Pharmacy (CCGP)

January 2006

Candidate Handbook • Candidate Handbook • Candidate Handbook

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All questions and requests for information about CCGP Certification should be directed to:

CCGP
1321 Duke Street
Alexandria, VA 22314-3563
703/535-3036
FAX 703/739-1500

All questions and requests for information about examination scheduling should be directed to:

Applied Measurement Professionals, Inc.
8310 Nieman Road
Lenexa, KS 66214
Voice: 913/541-0400
Fax: 913/541-0156
Website: www.goAMP.com

ABOUT CCGP

The Commission for Certification in Geriatric Pharmacy (CCGP) is a nonprofit corporation created in February 1997 by the American Society of Consultant Pharmacists (ASCP) Board of Directors. CCGP was created to oversee the certification program in geriatric pharmacy by establishing eligibility criteria and other program policies.

The CCGP Board of Commissioners is comprised of seven elected pharmacists; three appointed commissioners (consumer, and payor representative, and a physician with experience and/or credentialing in geriatric practice); one representative appointed by the American Society of Consultant Pharmacists (ASCP) Board of Directors, the ASCP Executive Director, and the CCGP Executive Director (ex officio). The membership of CCGP is comprised of individuals who have passed the Certification Examination in Geriatric Pharmacy and are credentialed.

ABOUT THIS HANDBOOK

This Candidate Handbook is only a guide. The information, procedures and fees detailed in this publication may be amended, revised or otherwise altered at any time and without advance notice by CCGP. The provision of this handbook does not confer any rights upon the applicant. For the most current version of this handbook, please visit www.ccgp.org or www.goAMP.com.

STATEMENT OF NONDISCRIMINATION POLICY

CCGP does not discriminate among applicants on the basis of age, gender, race, religion, national origin, disability, sexual orientation or marital status.

CERTIFICATION

The certification program in geriatric pharmacy is intended to recognize those pharmacists who demonstrate knowledge of geriatric pharmacotherapy and the knowledge and skills required to provide pharmaceutical care to the elderly. These pharmacists may practice in a variety of settings, including hospital, community or long-term care.

TESTING AGENCY

Applied Measurement Professionals, Inc. (AMP) is the professional testing agency contracted by CCGP to assist in the development, administration, scoring and analysis of the certification examination. AMP services also include the reporting of scores to candidates who take the examination. AMP is a research and development firm that conducts professional competency assessment research and provides examination services for a number of credentialing programs.

EXAMINATION POLICIES

CCGP offers the *Certification Examination in Geriatric Pharmacy* to individuals in geriatric pharmacy practice. The examination consists of 150 multiple-choice questions. Candidates will be allowed three hours to complete the examination. Individuals passing the Certification Examination in Geriatric Pharmacy are credentialed as Certified Geriatric Pharmacists (CGP).

CCGP with the advice and assistance of AMP prepares the examinations. Individuals with expertise in geriatric pharmacy practice write the questions and review them for relevancy, consistency, accuracy and appropriateness.

ELIGIBILITY REQUIREMENTS

To be eligible for the Certification Examination in Geriatric Pharmacy, an applicant must currently be a licensed pharmacist and must have a minimum of two years of experience as a licensed pharmacist. Applications must be accompanied by:

1) a photocopy of current state pharmacy registration certificate/license, and
2) a check, money order or credit card payment.

AUDIT PROCEDURE

CCGP reserves the right to audit any application submitted for the Certification Examination in Geriatric Pharmacy.

FOREIGN TRAINED/FOREIGN LICENSED APPLICANTS

Pharmacists who are not licensed to practice pharmacy in the United States may apply to take the Certification Examination in Geriatric Pharmacy. However, the practice analysis upon which the examination is based was conducted in the United States and CCGP does not claim that these processes or certification are accepted or recognized outside of the United States. Applicants who are not licensed to practice pharmacy in the United States must provide notarized documentation of their legal authorization to practice pharmacy in another country.

APPLICATION FEE

The Application Fee for the examination is $600. Fees may be paid by check or money order (made payable to CCGP), or by credit card (VISA, MasterCard, Discover or American Express). DO NOT SUBMIT CASH.

Candidates must submit the appropriate fee with the application form.

Returned checks and/or declined credit card transactions will be subject to a $25 handling fee. You must send a certified check or money order for the amount due, including the NSF fee, to CCGP to cover returned check and/or declined credit card transactions.

EXAMINATION ADMINISTRATION

The examination is delivered by computer at over 150 AMP Assessment Centers geographically located throughout the United States, Canada and Australia. Generally, there are no application deadlines and a candidate may submit an Application and Application Fee at any time. Testing is normally the first full week of each month. The examination is administered by appointment only Monday through Friday at 9:00 a.m. and 1:30 p.m. Available dates will be indicated when scheduling your examination. Candidates are scheduled on a first-come, first-served basis.

HOLIDAYS

The examinations are not offered on the following holidays:

New Year's Day
Martin Luther King Day
Presidents' Day
Good Friday
Memorial Day
Independence Day (July 4)
Labor Day
Columbus Day
Veterans' Day
Thanksgiving Day (and the following Friday)
Christmas Eve Day
Christmas Day
New Year's Eve Day

REGISTERING FOR AN EXAMINATION

Candidates should ensure that the CCGP Application has been properly completed and that the information provided is accurate. Your careful attention will enable prompt and efficient processing. Candidates will not be able to schedule an examination appointment with AMP until the Application has been processed. AMP will send written notification to registered candidates with examination scheduling procedures.

SCHEDULING AN EXAMINATION

After the candidate has received written confirmation from CCGP, there are two ways to schedule an appointment for the examination.

1. Schedule Online: The candidate may schedule an examination appointment online at any time by using AMP's online application/scheduling service. To use this service, follow these easy steps:
   - Go to www.goAMP.com and select "Candidates."
   - Follow the simple, step-by-step instructions to select your examination program and schedule an examination.

OR

2. Telephone Scheduling: Call AMP at 888/519-9901 to schedule an examination appointment. This toll-free number answered from 7:00 a.m. to 7:00 p.m. (Central Time) Monday through Thursday, 7:00 a.m. to 5:00 p.m. on Friday and 8:30 a.m. to 5:00 on Saturday.

When scheduling an examination, be prepared to confirm a location, a preferred date and time for testing, and to provide your Social Security number as a unique identification number. AMP will use your Social Security number only as an identification number in maintaining your record. When you contact AMP to schedule an examination appointment, you will be notified of the time to report to the Assessment Center. Please make a note of it because you will NOT receive an admission letter.

If you call AMP by 3:00 p.m. Central Time on...	Depending on availability, your examination may be scheduled beginning...
Monday	Thursday
Tuesday	Friday
Wednesday	Monday
Thursday	Tuesday
Friday	Wednesday

ASSESSMENT CENTER LOCATIONS

AMP Assessment Centers have been selected to provic accessibility to the most candidates in all states and major metropolitan areas. AMP Assessment Centers are typically located in H&R Block offices. International locations are also offered in Canada and Australia. A current listing of AMP Assessment Centers, including addresses and driving directions, may be viewed at AMP's website located at www.goAMP.com. Specific address information will be provided when a candidate schedules an examination appointment.

SPECIAL ARRANGEMENTS FOR CANDIDATES WITH DISABILITIES

CCGP and AMP comply with the Americans with Disabilities Act and strive to ensure that no individual with a disability is deprived of the opportunity to take the examination solely by reason of that disability. CCGP and AMP will provide reasonable accommodations for candidates with disabilities.

Wheelchair access is available at all Assessment Centers. Candidates with visual, sensory or physical disabilities that would prevent them from taking the examination under standard conditions may request special accommodations and arrangements. Candidates testing with approved special accommodations should schedule their test via AMP's toll-free number to ensure their accommodations are confirmed. Be sure to inform CCGP and AMP of your need for special accommodations when ca' ing to schedule your examination.

TELECOMMUNICATION DEVICES FOR THE DEAF

AMP is equipped with Telecommunication Devices for the Deaf (TDD) to assist deaf and hearing-impaired candidates. TDD calling is available 8:30 a.m. to 5:00 p.m. (Central Time) Monday-Friday at 913/495-4437. This TDD phone option is for individuals equipped with compatible TDD machinery.

EXAMINATION APPOINTMENT CHANGES

A candidate may reschedule an examination appointment at no charge **once** by calling AMP at 888/519-9901 at least four business days prior to the scheduled testing session. (See table below.)

If the examination is scheduled on...	AMP must be contacted by 3:00 p.m. Central Time to reschedule the examination by the previous...
Monday	Tuesday
Tuesday	Wednesday
Wednesday	Thursday
Thursday	Friday
Friday	Monday

MISSED APPOINTMENTS AND CANCELLATION

A candidate will forfeit the examination registration and all fees paid to take the examination under the following circumstances.

- The candidate wishes to reschedule an examination but fails to contact AMP at least four business days prior to the scheduled testing session,
- The candidate wishes to reschedule a second time,
- The candidate appears more than 15 minutes late for an examination, or
- The candidate fails to report for an examination appointment.

A complete Application and appropriate fee are required to re-register for the examination.

INCLEMENT WEATHER, POWER FAILURE OR EMERGENCY

In the event of inclement weather or unforeseen emergencies on the day of an examination, AMP will determine whether circumstances warrant the cancellation, and subsequent rescheduling, of an examination. The examination will usually not be rescheduled if the Assessment Center personnel are able to open the Assessment Center. If power to an Assessment Center is temporarily interrupted during an administration, your examination will restart where you left off and you may continue the examination.

Candidates may contact AMP's Weather Hotline at 913/495-4418 (24 hours/day) prior to the examination to determine if AMP has been advised that any Assessment Centers are closed. Every attempt is made to administer the examination as scheduled; however, should an examination be canceled at an Assessment Center, all scheduled candidates will receive notification following the examination regarding rescheduling or reapplication procedures.

PREPARING FOR THE EXAMINATION

Your primary objective in preparing for the examination is to pass. Other objectives such as learning new material and reviewing old material are critical toward this objective. Begin your study by developing your strategy for success.

A good study strategy includes preparation. To prepare, determine first what you need to learn, choose your study materials, and select a quiet, comfortable place that allows you to focus. Before you begin, check to make sure you have everything you need. Try to avoid interruptions for any reason.

Developing a study plan will allow you to learn the most as you study. Include setting goals in your study plan. Review what you have studied as often as possible. The more you review, the more you will retain.

Candidates may also wish to purchase GCGP's Self-Assessment Examination (SAE). The SAE is designed to help pharmacists measure their knowledge and skills in geriatric pharmacy practice. It will help identify those areas where additional continuing education may be helpful. It will also provide a candidate with a simulated experience in undertaking the actual certification examination. Once areas of additional continuing education would be helpful, candidates may wish to take advantage of a variety of resources such as www.geriatriacpharmacyreview.com to supplement existing knowledge. Please see page 13 for more information concerning the SAE.

TAKING THE EXAMINATION

Your examination will be given by computer at an AMP Assessment Center. You do not need any computer experience or typing skills to take your examination. On the day of your examination appointment, report to the Assessment Center no later than your scheduled testing time. Look for the signs indicating AMP Assessment Center Check-in. A CANDIDATE WHO ARRIVES MORE THAN 15 MINUTES AFTER THE SCHEDULED TESTING TIME WILL NOT BE ADMITTED.

IDENTIFICATION

To gain admission to the Assessment Center, you must present two forms of identification, one with a current photograph. Both forms of identification must be current and include the candidate's current name and signature. The candidate will be required to sign a roster for verification of identity.

Acceptable forms of photo identification include a current driver's license with photograph, a current state identification card with photograph, a current passport, or a current military identification card with photograph. Employment ID cards, student ID cards and any type of temporary identification are NOT acceptable as the primary form of identification.

You must have proper identification to gain admission to the Assessment Center. Failure to provide appropriate identification at the time of the examination is considered a missed appointment. There will be no refund of your examination fee.

SECURITY

CCGP and AMP maintain examination administration and security standards that are designed to assure that all candidates are provided the same opportunity to demonstrate their abilities. The Assessment Center is continuously monitored by audio and video surveillance equipment for security purposes.

The following security procedures apply during the examination:

- Examinations are proprietary. No cameras, notes, tape recorders, Personal Digital Assistants (PDAs), pagers or cellular phones are allowed in the testing room.
- Hand-held, silent, non-printing, battery-operated calculators may be used. Candidates may NOT use calculators which have either word processing or word storage capabilities (complete A-Z keypad). All calculators will be examined by the proctor before a candidate is admitted to the examination area. Candidates are responsible for providing their own calculators. Candidates cannot share calculators during the examination.
- No guests, visitors or family members are allowed in the testing room or reception areas.
- No personal items, valuables, or weapons should be brought to the Assessment Center. Only keys and wallets may be taken into the testing room and AMP is not responsible for items left in the reception area.

EXAMINATION RESTRICTIONS

- No personal belongings will be allowed in the Assessment Center. Pencils will be provided during check-in.
- You will be provided with scratch paper to use during the examination. You must return the scratch paper to the supervisor at the completion of testing, or you will not receive a score report. No documents or notes of any kind may be removed from the examination room.
- No questions concerning the content of the examination may be asked during the examination.
- Eating, drinking or smoking will not be permitted in the Assessment Center.
- You may take a break whenever you wish, but you will not be allowed additional time to make up for time lost during breaks.

MISCONDUCT

Individuals who engage in any of the following conduct may be dismissed from the examination, their scores will not be reported and examination fees will not be refunded. Examples of misconduct are when a candidate:

- creates a disturbance, is abusive, or otherwise uncooperative;
- displays and/or uses electronic communications equipment such as pagers, cellular phones, PDAs;
- gives or receives help or is suspected of doing so;
- attempts to record examination questions or make notes;
- attempts to take the examination for someone else; or
- is observed with notes, books or other aids.

COPYRIGHTED EXAMINATION QUESTIONS

All examination questions are the copyrighted property of CCGP. It is forbidden under federal copyright law to copy, reproduce, record, distribute or display these examination questions by any means, in whole or in part. Doing so may subject you to severe civil and criminal penalties.

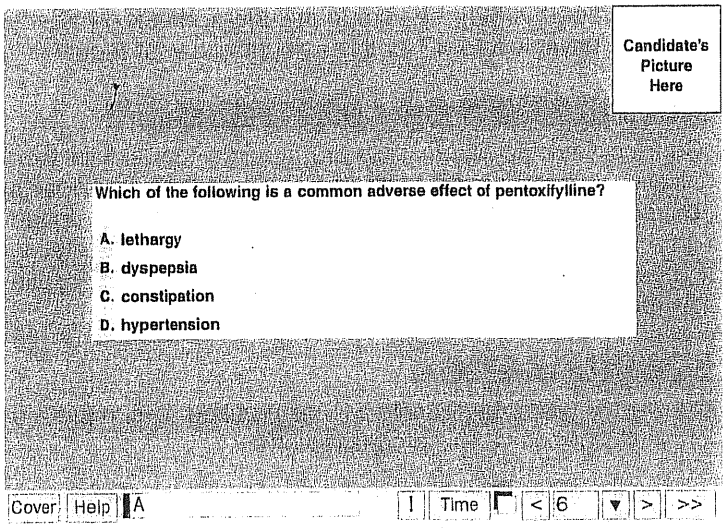
PRACTICE EXAMINATION

After your identification has been confirmed, you will be directed to a testing carrel. You will be instructed on-screen to enter your Social Security number. You will take your photograph which will remain on screen throughout your examination session. This photograph will also print on your score report.

Prior to attempting the examination, you will be given the opportunity to practice taking an examination on the computer. The time you use for this practice examination is NOT counted as part of your examination time or score. When you are comfortable with the computer testing process, you may quit the practice session and begin the timed examination.

TIMED EXAMINATION

F ving the practice examination, you will begin the timed examination. Before beginning, instructions for taking the examination are provided on-screen.



The computer monitors the time you spend on the examination. The examination will terminate if you exceed the time allowed. You may click on the "Time" box in the lower right-hand corner of the screen or select the Time key to monitor your time. A d l clock indicates the time remaining for you to complete th xamination. The Time feature may be turned off during the examination.

Only one examination question is presented at a time. The question number appears in the lower right hand corner of the screen. Choices of answers to the examination question are identified as A, B, C, or D. You must indicate your choice by either typing in the letter in the response box in the lower left hand of the computer screen or clicking in the option using the mouse. To change your answer, enter a different option by pressing the A, B, C, or D key or by clicking on the option using the mouse. You may change your answer as many times as you wish during the examination time limit.

To move to the next question, click on the forward arrow (>) in the lower right portion of the screen or select the NEXT key. This action will move you forward through the examination question by question. If you wish to review any question or questions, click the backward arrow (<) or use the left arrow key to move backward through the examination.

An examination question may be left unanswered for return later in the examination session. Questions may also be bookmarked for later review by clicking in the blank square to the right of the Time button. Click on the hand icon or select the NEXT key to advance to the next unanswered or bookmarked question on the examination. To identify all unanswered and bookmarked q tions, repeatedly click on the hand icon or press the N . key. When the examination is completed, the number of examination questions answered is reported. If not all questions have been answered and there is time remaining, return to the examination and answer those questions. Be sure to provide an answer for each examination question before ending the examination. There is no penalty for guessing.

CANDIDATE COMMENTS

During the examination, online comments may be provided for any question by clicking on the button displaying an exclamation point (!) to the left of the Time button. This opens a dialogue box where comments may be entered. Comments will be reviewed, but individual responses will not be provided.

FOLLOWING THE EXAMINATION

After completing the examination, candidates are asked to complete a short evaluation of their examination experience. Then, candidates are instructed to report to the examination proctor to receive their score report. Scores are reported in written form only, in person or by U.S. mail. Scores are not reported over the telephone, by electronic mail or by facsimile.

Your score report will indicate a "pass" or "fail." Your pass/fail status is determined by your raw score. Additional detail is provided in the form of raw scores by major content category. A raw score is the number of questions you answered correctly.

PASS/FAIL SCORE DETERMINATION

Examination scores are reported as raw scores and scaled scores. A raw score is the number of correctly answered questions; a scaled score is statistically derived from the raw score. Your total score determines whether you pass or fail; it is reported as a scaled score ranging between 0 and 99.

The minimum scaled score needed to pass the examination has been set at 75 scaled score units. The reason for reporting scaled scores is that different forms (or versions) of the examination may vary in difficulty. As new forms of the examination are introduced each year, a certain number of questions in each content area are replaced. These changes may cause one form of the examination to be slightly easier or harder than another form. To adjust for these differences in difficulty, a procedure called "equating" is used. The goal of equating is to ensure fairness to all candidates.

In the equating process, the minimum raw score (number of correctly answered questions) required to equal the scaled passing score of 75 is statistically adjusted (or equated). For instance, if the examination is determined to be more difficult than the previous form of the examination, then the minimum raw passing score required to pass will be slightly lower than the original raw passing score. If the examination is easier than the previous form of the examination, then the minimum raw score will be higher. Equating helps to assure that the scaled passing score of 75 represents the same level of competence no matter which form of the examination a candidate takes.

In addition to the candidate's total scaled score and scaled score required to pass, raw scores (the actual number of questions answered correctly) are reported for the major categories on the content outline. The number of questions answered correctly in each major category is compared to the total number of questions possible in that category on the score report (e.g., 15/20). Content categorical information is provided to assist candidates in identifying areas of relative strength and weakness; however, passing or failing the examination is based only on the candidate's total scaled score.

SCORES CANCELLED BY CCGP OR AMP

CCGP and AMP are responsible for the validity and integrity of the scores they report. On occasion, occurrences, such as computer malfunction or misconduct by a candidate, may cause a score to be suspect. CCGP and AMP reserve the right to void or withhold examination results if, upon investigation, violation of its regulations is discovered.

IF YOU PASS THE EXAMINATION

If you pass the examination, CCGP will request that you sign a Declaration on the Appropriate use of the Credential and remit a five-year certification fee. Following receipt of the Declaration and fee, CCGP will send a Certificate, in your name, officially designating you as a Certified Geriatric Pharmacist.

IF YOU DO NOT PASS THE EXAMINATION

There is no limit to the number of times candidates may attempt the examination. If you were unsuccessful in your examination attempt, you may reregister once every 90 days by completing another Application and submitting appropriate fees. The fee to retake the examination after an unsuccessful attempt is $300, if the examination is retaken within two years. After two years, the full fee ($600) must be paid.

FAILING TO REPORT FOR AN EXAMINATION

A candidate who fails to report for an examination forfeits all fees paid to take the examination. A completed application and examination fee are required to reapply for examination.

CONFIDENTIALITY

Information about candidates for testing and their examination results are considered confidential. Individual examination scores are released ONLY to the individual candidate. Questions concerning examination results should be referred to the CCGP Candidate Services Department in writing.

RECOGNITION OF CERTIFICATION

Candidates who pass the certification examination are entitled to use the designation "CGP" for Certified Geriatric Pharmacist. CCGP will provide certificants with a certificate of recognition suitable for framing. In addition, certificants will be entitled to additional items, such as lapel pins, that display the logo for Certified Geriatric Pharmacist. Contact CCGP for additional information.

QUESTIONS ABOUT THE EXAMINATION

Candidates may not have access to the examinations or to specific questions except during administration of the examination. Candidates may comment on any question, the administration of the examination or the test center facilities on their answer sheet on the day of the examination. Individual responses to question comments will not be provided.

DUPLICATE SCORE REPORTS

Requests for duplicate score reports must be made in writing to AMP within one year of the examination date. Your request must include your name, social security number, mailing address, examination date, test center and signature. The fee for a duplicate score report is $25; be sure to include a check or money order made payable to AMP for this amount with your request.

CONTINUATION OF CERTIFICATION

All Certified Geriatric Pharmacists are required to maintain their certification, in good standing with the CCGP. To do so, certificants will be requested to submit an annual questionnaire and a signed Attestation of a Valid License. Failure to submit a signed Attestation may jeopardize the certificant's good standing with CCGP, ultimately resulting in suspension of their certified standing.

RECERTIFICATION

Every five (5) years, certificants will be required to complete a recertification process. This process involves:

1) paying the $600 Recertification Application Fee and achieving a passing score on a multiple-choice objective examination, based on the content outline of the Certification Examination in Geriatric Pharmacy

OR

2) paying the $600 Recertification Application Fee and successfully completing the Professional Development Program for CGP Recertification. Please visit the CCGP website for further information on this program at www.ccgp.org. Recertification is required to provide assurance that practitioners are maintaining their knowledge and skills in geriatric pharmacy practice.

RECERTIFICATION GRACE PERIOD

If a CCGP Certified Geriatric Pharmacist (CGP) fails to successfully complete the recertification process, extension of her/his certification may be granted for six months while he/she seeks to successfully complete the process. If a CCGP certified pharmacist does not complete the process within that period, then the individual's status as a CGP will lapse. Once certification has lapsed, reinstatement can be achieved only by successfully completing the entire certification process.

EXAMINATION CONTENT

To begin your preparation in an informed and organized manner, you should know what to expect from the actual examination in terms of the content. Information regarding the content of the examination is presented in this handbook. The content outline will give you a general impression of the examination and, with closer inspection, can give you specific study direction by revealing the relative importance given to each category on the examination.

Note: Medications on the certification examination will be referred to by the generic name only (USAN or USP name). Medication which are known by the British Approved Name outside the United States will have this name in parentheses. For example: albuterol (salbutamol). Laboratory examination results will be presented in both conventional and international units. The content for the examination is based on a job analysis and is described in the following detailed content outline.

Certified Geriatric Pharmacist Detailed Content Outline

[1] Percentages for minor content area are approximate, and based on the number of items in that section.
[2] Shaded "X" denotes that NO items should be written at the indicated cognitive level for the task.

	QUESTIONS			
	Recall	Application	Analysis	TOTAL %
I. PATIENT SPECIFIC ACTIVITIES	**12**	**25**	**15**	**35%**
A. Collect and Evaluate Patient-Specific Information	**2**	**7**	**2**	**21%**
1. Interpret and apply knowledge of the following to the provision of pharmaceutical care for older adults:				
a. incidence of disease, comorbidity and disability			X[2]	
b. patterns of medication use			X	
c. causes of morbidity and mortality			X	
2. Assess and apply understanding of the following issues to the provision of pharmaceutical care for older adults:				
a. continuum of care			X	
b. wellness and health promotion			X	
c. loss of independence			X	
d. end of life issues (advance directives, treatment issues, quality of life choices)			X	
e. ethical issues				
3. Evaluate the social aspects of aging in the provision of pharmaceutical care for older adults related to the following:				
a. economic issues			X	
b. availability of community based services (referrals and triage)			X	
c. isolation			X	
d. losses			X	
e. role of caregiver				
4. Communicate with elderly patients, their caregivers and healthcare professionals:				
a. recognize communication barriers including age-related sensory and cognitive impairments, illiteracy, and language and cultural differences		X	X	
b. apply strategies to overcome communication barriers			X	
c. apply privacy and confidentiality principles			X	
d. ensure patient understanding of prescribed therapy				
5. Evaluate physiological changes that accompany aging (e.g., sensory, body composition, organ system function)			X	
6. Interpret and monitor laboratory results and procedures for the older patient				
7. Evaluate and apply results of standardized assessment tools (MMSE, GDS, etc.)				
8. Recognize and assess altered disease state presentations in the elderly			X	
9. Recognize and assess altered psychological status in the elderly			X	
10. Identify and assess compliance/adherence issues affecting potential treatment plans (e.g., memory loss, sensory changes, hearing, cognition, patient beliefs, economics, and learning disabilities)				
11. Obtain an accurate drug history including over the counter and alternative/complementary medications		X	X	
12. Obtain and/or evaluate relevant physical assessment information			X	
13. Apply principles of pharmacokinetic and pharmacodynamic changes associated with aging to the design of the pharmacotherapy regimen				
B. Identify, Resolve and Prevent Medication Therapy – Related Problems	**3**	**3**	**10**	**31%**
1. Untreated or under-treated conditions				
2. Improper drug selection				
3. Subtherapeutic or Supratherapeutic dosage				
4. Compliance/Adherence issues:				
a. monitor patient's compliance/adherence with medications and apply strategies to educate the patient and/or caregiver, and encourage compliance/adherence with therapy			X	
b. promote elder-appropriate drug labeling and packaging			X	

Certified Geriatric Pharmacist Detailed Content Outline [1] Percentages for minor content area are approximate, and based on the number of items in that section. [2] Shaded "X" denotes that NO items should be written at the indicated cognitive level for the task.	QUESTIONS			
	Recall	Application	Analysis	TOTAL %
5. Adverse drug events				
6. Drug interactions				
7. Drug use without indication				
8. Treatment failures				
C. Determine Patient's Pharmaceutical and Related Health Care Needs and Integrate into Care Plan	0	1	2	6%
D. Select Drug Therapy Goals which Focus on Function and Quality of Life	1	2	X	6%
E. Design and Implement a Therapeutic Regimen in Collaboration with the Patient and Other Health Care Professionals	1	5	1	13%
1. Apply concept of risk: benefit for each drug				
2. Recommend non-prescription drugs			X	
3. Educate patient on therapy options – generics, alternative therapies, nondrug therapies, formulary options, etc.			X	
4. Educate patient on medication-related problems (e.g., side effects of medication, drug interactions)			X	
5. Recognize need for referral to specialized healthcare provider for further evaluation/treatment			X	
F. Patient Monitoring Plan	5	7	0	23%
1. Design plan to monitor for safety, effectiveness and achievement of therapeutic goals			X	
2. Implement plan			X	
3. Evaluate its effects on quality of life issues				
4. Document steps and outcomes of pharmaceutical care plan		X	X	
II. DISEASE SPECIFIC ACTIVITIES	20	43	17	53%
A. Cardiovascular Disorders – e.g., Hypertension, Heart Failure, Ischemic Heart Disease, Myocardial Infarction, Cardiac Arrhythmias, Hyperlipidemia, Peripheral Vascular Disease	2	5	2	11%
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
B. Dermatologic Disorders – e.g., Pressure Ulcers, Drug Induced Skin Disorders, Xerosis, Fungal Rashes, Other Common Skin Disorders	1	1	0	3%
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
C. Endocrine and Exocrine Disorders – e.g., Thyroid Disorders, Diabetes Mellitus, SIADH, Disorders of the Adrenal Gland, Paget's Disease, Hormone Replacement Therapy	2	4	2	10%
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				

Certified Geriatric Pharmacist Detailed Content Outline

[1] Percentages for minor content area are approximate, and based on the number of items in that section.
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	QUESTIONS			
	Recall	Application	Analysis	TOTAL %
D. Gastrointestinal Disorders- e.g., Peptic Ulcer Disease, Gastro-Esophageal Reflux Disease, Diarrhea and Constipation, Irritable Bowel Syndrome, Inflammatory Bowel Disease, Hepatic Disorder (Cirrhosis), Pancreatitis, Cholelithiasis	1	4	1	7%
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
E. Hematologic Disorders – e.g., Anemias, Disorders of Hemostasis, Thrombocytopenia, Disorders of White Blood Cells	1	2	1	5%
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
F. Infectious Diseases – e.g., Pneumonia, Urinary Tract Infection, Tuberculosis, Herpes Zoster, AIDS, Skin and Soft Tissue Infections, Hepatitis, Bone and Joint Infections, Genitourinary Tract Infection, Influenza, Ophthalmic Infections, Nosocomial Infections, Drug Resistance, Immunizations	2	3	2	9%
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
G. Musculoskeletal Disorders – e.g., Osteoarthritis, Rheumatological Diseases, Osteoporosis, Gout, Acute and Chronic Pain, Foot Disorders	2	4	2	10%
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
H. Neurological Disorders – e.g., Cerebrovascular Disease (Stroke, Transient Ischemic Attacks), Movement Disorders (Parkinson's Disease, Essential Tremor), Dementias (Alzheimer's Disease, Lewy Body Disease, Ischemic Vascular Dementia), Delirium, Seizure Disorders, Neuropathies, Acute and Chronic Pain Syndromes	2	5	2	11%
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				

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[1] Percentages for minor content area are approximate, and based on the number of items in that section.
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	QUESTIONS			
	Recall	Application	Analysis	TOTAL %
I. Nutrition and Hydration Disorders – e.g., Malnutrition, Dehydration, Fluid and Electrolyte Disorders	**1**	**2**	**1**	**5%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
J. Oncology – e.g., Breast Cancer, Skin Cancer, Prostate Cancer, Lung Cancer, Colorectal Cancer, Brain Tumors	**1**	**1**	**0**	**3%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
K. Ophthalmology – e.g., Glaucoma, Dry Eyes, Blepharitis, Macular Degeneration, Cataracts	**1**	**1**	**0**	**3%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
L. Psychiatric Disorders – e.g., Depression and Other Mood Disorders, Schizophrenia and Other Psychotic Disorders, Sleep Disturbances, Anxiety Disorders, Behavioral Disorders, Alcohol and Drug Abuse	**2**	**5**	**2**	**11%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
M. Genitourinary Disorders – e.g., Urinary Incontinence, Benign Prostatic Hyperplasia, Sexual Dysfunction, Renal Failure	**1**	**3**	**1**	**6%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
N. Respiratory Disorders – e.g., Chronic Obstructive Pulmonary Disease, Asthma	**1**	**3**	**1**	**6%**
1. Recognize common signs and symptoms		X	X	
2. Apply disease-specific knowledge to management of patients (e.g., epidemiology, risk factors, pathogenesis and pathophysiology, diagnostic/prognostic issues, clinical course, available practice guidelines, pharmocoeconomics, quality of life, patient satisfaction)			X	

Certified Geriatric Pharmacist Detailed Content Outline [1] Percentages for minor content area are approximate, and based on the number of items in that section. [2] Shaded "X" denotes that NO items should be written at the indicated cognitive level for the task.	QUESTIONS			
	Recall	Application	Analysis	TOTAL %
3. Design and recommend patient-specific pharmacotherapy considering comorbidity and other factors				
4. Evaluate drug response using effectiveness and safety endpoints, quality of life issues and recommend modifications in therapy as necessary				
III. POPULATION SPECIFIC ACTIVITIES	**5**	**5**	**8**	**12%**
A. Research	**1**	**1**	**4**	**33%**
1. Conduct drug use evaluations (DUE) and drug use review (DUR)			X	
2. Apply DUE/DUR results to improve the quality of care			X	
3. Evaluate and apply research pertinent to the elderly				
4. Interpret and apply geriatric practice guidelines				
B. Economics and Access	**1**	**1**	**3**	**28%**
1. Develop and implement formulary management/protocols				
2. Interpret pharmacoeconomic data			X	
3. Develop and implement practice guidelines				
4. Evaluate costs/benefits issues that influence access to medications or therapy for specific patients				
C. Health Policy	**3**	**3**	**1**	**39%**
1. Communicate with healthcare professionals to improve quality of care			X	
2. Ensure that privacy and confidentiality standards are maintained		X	X	
3. Optimize the Continuum of Care process				
TOTAL TEST	**37**	**73**	**40**	**100%**

SAMPLE QUESTIONS

1. Which of the following is a common adverse effect of pentoxifylline?

   A. lethargy
   B. dyspepsia
   C. constipation
   D. hypertension

2. Which of the following drugs is most likely to contribute to falls in an elderly patient?
   A. aspirin
   B. alenodronate
   C. prazosin HCl
   D. cefadroxil monohydrate

3. Which of the following should be included in the documentation of a pharmaceutical care plan?

   1. the decision-making process that has been used
   2. any interventions that have been made
   3. a description of patient-specific outcomes

   A. 1 and 2 only
   B. 1 and 3 only
   C. 2 and 3 only
   D. 1, 2, and 3

4. Which of the following is the recommended daily intake of elemental calcium for postmenopausal women, who are not taking hormone replacement therapy?

   A. 500 mg
   B. 1000 mg
   C. 1500 mg
   D. 2000 mg

5. An elderly man with diabetes mellitus presents with cellulitis of the lower right leg. The patient is started on cephalexin HCl 500 mg po q6h with no significant improvement after 5 days of treatment. Which of the following is the most appropriate antibiotic for this patient?

   A. cefixime
   B. ciprofloxacin
   C. co-trimoxazole
   D. amoxicillin/clavulanate potassium

Answer Key:

1. B 2. C 3. D 4. C 5. D

SELF-ASSESSMENT EXAMINATION

CCGP offers a Self-Assessment Examination (SAE) to help candidates prepare for the Certification Examination in Geriatric Pharmacy. The SAE is available in an online, Web-based format and in paper-and-pencil, booklet format.

WHO SHOULD USE THE SELF-ASSESSMENT EXAMINATION?

1. • **Candidates** – Evaluate your readiness for taking the proctored certification examination.
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3. • **Pharmacists** – Assess your knowledge and skills in geriatric pharmacy practice.
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For more information about the Web-based SAE, please visit www.ccgp.org and click on the link "Self Assessment Program." To order a copy of the paper-and-pencil SAE, complete the order form in the back of this handbook.

RECOMMENDED REFERENCES

The BCGP Examination Development Committee recommends the following references as useful in learning the basics of geriatric pharmacy practice. This list does not attempt to include all acceptable references, nor is it suggested that the Certification Examination in Geriatric Pharmacy is necessarily based on these references. You should obtain the most current edition available.

General Pharmacotherapy

Applied Therapeutics: The Clinical Use of Drugs. Koda-Kimble MA and Young LY.

Pharmacotherapy: A Pathophysiologic Approach. DiPiro JT, et. al.

Geriatrics

Essentials of Clinical Geriatrics. Kane RL, Ouslander JG, and Abrass IB. New York: McGraw-Hill. ISBN 0-07-033473-0. Available from ASCP. Order phone 800/355-2727. $36.

Merck Manual of Geriatrics. Abrams WB, Beers MH, et.al., eds. Whitehouse Station: Merck and Company. ISBN 0-911910-66-2. Order phone 800/659-6598. $25.

Principles of Geriatric Medicine and Gerontology. Hazzard WR, et.al., eds. ISBN 0-07-027501-7. Available from ASCP, order phone 800/355-2727. $142.50.

Practice Guidelines

The federal Agency for Healthcare Research and Quality (AHRQ) has practice guidelines on pertinent topics, such as heart failure and pressure sores. You may contact AHRQ at 800/358-9295, or on the web at www.ahrq.gov.

The National Guideline Clearinghouse is a web site sponsored by AHRQ that contains hundreds of practice guidelines developed by a wide variety of organizations. This web site is located at www.guideline.gov.

Certification Examination in Geriatric Pharmacy
EXAMINATION APPLICATION

Applicant Status

Please indicate whether you are a NEW APPLICANT, REAPPLICANT or RECERTIFICATION Candidate for the Certification Examination in Geriatric Pharmacy:

☐ NEW APPLICANT

☐ REAPPLICANT: The last time I attempted the Certification Examination in Geriatric Pharmacy was: _____ (mm/dd/yyyy)

☐ RECERTIFICATION Candidate:
☐ By Examination ☐ By Continuing Education

Fees: Indicate the appropriate fee(s).

☐ New Applicant Examination Fee $600

☐ Reapplicant Examination Fee (if taken within two years) $300

☐ Recertification Candidates Fee (Examination or Continuing Education) $600

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☐ Check (payable to CCGP)

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☐ Credit Card Type:
Please select one: ☐ VISA ☐ MasterCard
☐ Discover ☐ American Express

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Name: _____
(First, Middle Initial, Last, Generation)

Gender: ☐ Male ☐ Female

Former Name: (if applicable) _____

Social Security Number: _____–_____–_____

Date of Birth: mm/dd/yy _____

Daytime Phone: _____ Evening Phone: _____

E-mail: _____

Preferred Mailing Address

Is this address: ☐ Home ☐ Business

Address _____

Address _____

City_____ State_____ Zip_____ Country_____

Special Examination Requests

☐ Special ADA Accommodation Request (please complete form and submit with your application and fees)

Signature

By submitting this application, I certify that I have read all portions of the Candidate Handbook and application. I certify that the information I have submitted in the application and the documents I have enclosed are complete and correct to the best of my knowledge and belief. I certify that I have a minimum of two years experience as a licensed pharmacist. I understand that if the information I have submitted is found to be incomplete or inaccurate, my application may be rejected or my examination results may be delayed, not released or invalidated by CCGP.

Signature: _____ Date: _____

Complete this form and submit it to Candidate Services, CCGP, 1321 Duke Street, Alexandria, VA 22314-3563 with the required fee.

REQUEST FOR SPECIAL EXAMINATION ACCOMMODATIONS

If you have a disability covered by the Americans with Disabilities Act, please complete this form and the Documentation of Disability-related Needs on the reverse side so your accommodations for testing can be processed efficiently. The information you provide and any documentation regarding your disability and your need for accommodation in testing will be treated with strict confidentiality.

Applicant Information

Social Security # _____ – _____ – _____ Test Center _____

Last Name _____ First Name _____ Middle Name _____

Address _____

City _____ State _____ Zip Code _____

Special Accommodations

I request special accommodations for the _____ / _____ administration of the _____ examination(s).
Month Year

Please provide (check all that apply):

_____ Accessible testing site
_____ Special seating
_____ Large print test
_____ Reader
_____ Circle answers in examination booklet
_____ Extended testing time (time and a half)
_____ Separate testing area
_____ Other special accommodations (please specify)

_____

_____

_____

Comments: _____

_____

_____

Signed: _____ **Date:** _____

Return this form with your examination application to:
Candidate Services Department, CCGP, 1321 Duke Street, Alexandria, VA 22314-3563.
If you have questions, call the Candidate Services Department at 703/535-3036.

DOCUMENTATION OF DISABILITY-RELATED NEEDS

Please have this section completed by an appropriate professional (education professional, doctor, psychologist, psychiatrist) to ensure that AMP is able to provide the required examination accommodations.

Professional Documentation

I have known _____ since _____ / _____ / _____ in my capacity as a
Examination Applicant Date

_____.
Professional Title

The applicant discussed with me the nature of the examination administered. It is my opinion that because of this applicant's disability described below, he/she should be accommodated by providing the special arrangements listed on the reverse side.

Description of Disability: _____

_____

_____

_____

_____

Signed: _____ **Title:** _____

Date: _____ **License # (if applicable):** _____

Return this form with your examination application to:
Candidate Services Department, CCGP, 1321 Duke Street, Alexandria, VA 22314-3563.
If you have questions, call the Candidate Services Department at 703/535-3036.

PAPER-AND-PENCIL SELF-ASSESSMENT EXAMINATION ORDER FORM

CCGP offers a Self-Assessment Examination (SAE) to help pharmacists assess their knowledge and skills in geriatric pharmacy practice and help candidates prepare for the Certification Examination in Geriatric Pharmacy. The SAE is available in an online, Web-based format and in paper-and-pencil, booklet format. For more information about the Web-based SAE, please visit www.ccgp.org and click on the link "Self Assessment Program." To order a copy of the paper-and-pencil SAE, please complete this form and fax with payment to CCGP at 703/739-1500.

The SAE consists of 150 multiple-choice questions, is self-scoring, and is based on the current certification examination content outline. Candidates receive total scores and a summary of strengths and weaknesses by content area. The SAE also contains explanations for each correct and incorrect answer helping you to better understand the reasoning that supports the correct therapy.

Price

CCGP Members $65/copy

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Tax: VA residents add 4.5%. Shipping & handling included.

Name_____ Certification Number _____

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Commission for Certification in Geriatric Pharmacy (CCGP)
1321 Duke Street
Alexandria, VA 22314-3563
703/535-3036
FAX 703/739-1500

Applied Measurement Professionals, Inc. (AMP)
8310 Nieman Road
Lenexa, Kansas 66214-1579
913/541-0400
FAX 913/541-0156

Attachment 4

Proposed Board of Pharmacy Compounding Regulations With Comments Submitted to the Licensing Committee, March 7, 2007

§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.

As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:

(a) "Reasonable quantity" means that quantity of an unapproved drug which:

(1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and

(2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and

(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.

(b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.

(c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.

§1716.2. Record Requirements--Compounding for Future Furnishing.

(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

(1) The date of preparation.

(2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.

(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(4) The signature or initials of the pharmacist performing the compounding.

(5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.

(6) The name(s) of the manufacturer(s) of the raw materials.

(7) The quantity in units of finished products or grams of raw materials.

(8) The package size and the number of units prepared.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.

CPHA: Comments with General Applicability:

1) The proposed language contains several references to either "expiration date" or "beyond use date." These references should be amended so that only one term is used, which, based on industry usage and trends, we believe should be "beyond use date."
2) There are several sections which require "written" documentation of some sort. These sections should be changed to "readily retrievable" in order to allow records to be kept electronically rather than require retention of paper documents.

Article 4.5 General Compounding

§1735. Definitions

(a) "Compounding" means any of the following activities occurring in a pharmacy pursuant to a prescription:
  (1) Altering the dosage form or delivery system of a drug
  (2) Altering the strength of a drug
  (3) Combining components or active ingredients

DENNIS MING: **into a drug product not commercially available**

  (4) Preparing a drug product from bulk chemicals

Compounding does not include the reconstitution of a drug pursuant to the manufacturer's direction for oral, rectal or topical administration.

Dan Wills: I notice that flavoring was taken out. I remember that being done since many of the chains are now flavoring. However, I have also heard stories by pharmacies that have had to fix problems associated with flavoring of meds by non-compounders. Most of the time it has to do with interactions of the flavoring agent or actually making the flavor worse. Do we want to re-look at this?

Compounding" means any of the following activities occurring in a pharmacy pursuant to a prescription *or in anticipation of a prescription based on past history*: I can't find anything that allows us to make preparations in a larger batch. This is sometimes needed for accuracy and safety, particularly when there is a very small dosage or therapeutic range. Business principles will stop people from making more than they will reasonably use. That would only incur waste. By putting past history in it, there would be an adjustment for the size of the operation. If a pharmacy only does one of these a week, they probably shouldn't make very much. If the demand is high however, and it can be proven historically, then a larger batch would make more sense. It also eliminates a regulatory punishment for success.

(b)"Integrity" means the drug will retain its effectiveness until the beyond use date noted on the label.

Dan Wills: "...will retain its **effectiveness**..." Aren't there cases where therapeutically a drug will become less effective even though it is still full strength? I would suggest changing to "...will retain it its *potency*..."

(c) "Quality" means the drug is free of any contaminants and only contains those active ingredients indicated on the label.

Dan Wills: "...drug is free of **any** contaminants..." Should be changed to "*harmful levels*" or something similar. The air we breath has 100,000 contaminants in a cubic foot. Even sterile compounding laws allow us to have endotoxins as long as they are non-pyrogenic. Making something free of any contaminants is impossible.

(d) "Strength" means the amount of active ingredient in each unit of the drug.

(e) As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:

(1) "Reasonable quantity" means that quantity of an unapproved drug which:

(A) is sufficient for that prescriber's office use; and

(B) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and

(C) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for strength, quality and integrity of the compounded medication.

(2) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.[1]

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, and 4052, Business and Professions Code.

§1735.1. Requirements

(a) Prior to compounding a drug, the dispensing pharmacist shall establish a professional relationship with the prescriber and patient.

Dan Wills: "...pharmacist shall establish a **professional relationship,** *as evidenced by a valid prescription,* with the prescriber and patient." Does a prescription constitute a professional relationship? If not, this would be difficult to define. Would it mean a phone call? A personal visit? Taking them out to dinner? If a prescription is not good enough, we are being held to a higher standard than other pharmacists. When a prescription is brought in by the patient, or transmitted from a doctor, there is no question of a relationship. There is just an implied relationship and it is just filled. Also, this wording puts the burden on the pharmacist to create the relationship. What if a veterinarian who we have not met, calls us and prescribes for Fluffy who we have also never had an interaction with? What would need to be done? If anything more than a valid prescription is required to "establish a relationship," we will hurt many patients in rural areas who do not have immediate access to the pharmacy.

CPHA: (a) belongs in a separate section.

(b) A drug may not be compounded without a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.
(2) Inactive ingredients to be used.
(3) Process and/or procedure used to prepare the drug.
(4) Quality reviews required at each step in preparation of the drug.

Dan Wills: "...quality reviews at each *appropriate* step in the preparation." This allows for professional judgment.
CPHA: change to: "Quality reviews required at appropriate steps in the preparation of the compounded preparation." Not all steps in the compounding process require quality review.

(5) Post compounding process or procedures required, if any.
(6) Beyond use dating requirements.

[1] Moved from 1716.1

(c) The pharmacist shall be responsible for assuring that the compounded drug retains its strength, quality, and integrity until dispensed.

(d) All chemicals, drug products, and components must be used and stored according to compendial and other applicable requirements to maintain their strength, quality and integrity.

(e) The beyond use date of the finished product must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies of drugs using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

Dan Wills: ".. supported by **stability studies**..." Can we change this to "...supported by stability *and/*or *potency studies*...?" Recently there has been a lot of talk about this subject on the IJPC network as well as with testing labs. A stability study will costs thousands of dollars to find out all the degradants (sp?) in the medicine. Currently when we send something in for testing, we will check for potency and if appropriate sterility and pyrogenicity. I know that stability studies would be better, but if a capsule we make still tests out to be just as potent in one year as on day one, why not put that on the container? Especially if the bulk powder doesn't expire for 10 years. Stability studies are used in manufacturing. They are not standard procedure in compounding. We need to start gathering stability studies from the entire industry, but That will be a slow process. If potency is good at day one, why not OK at day 365?

We have a doctor that invented a vitamin B5/B6 cream. After a couple of weeks it oxidizes. He has had it tested, and found it to be just as potent as far as the vitamin is concerned and it still works for his patients. However, the drug is not stable, because of the oxidization. Here is a case where it would fail stability, yet be therapeutically effective. Isn't that the real issue? By adding potency to the regulations we eliminate the "pull it out of the air" approach, can have some scientific basis for a date, yet allow for professional judgment. Isn't that what you paid the big bucks at school for?

CPHA: (e) Eliminate the word "stability" before "studies" in the third line. The expense of a formal "stability study" is not an appropriate requirement; what is needed is some form of study that supports an extended beyond use date for a compounded drug product.

~~(f) A pharmacy may contract with another pharmacy to compound drug products, pursuant to a prescription, for delivery to another pharmacy. The compounded product must be labeled with the name of the pharmacy that compounded the drug and the information required by Business and Professions Code Section 4076.~~

(g) Pharmacists who compound drugs, or supervise the compounding of drugs, shall be responsible for ensuring that the compounded drug has been prepared, labeled, stored, and delivered properly.

(h) Prior to allowing any drug to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board (form XXXXX). The self assessment shall subsequently be performed before July 1 of each year, within 30 days of the designation of a new pharmacist-in-charge, or within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4052, and 4076, Business and Professions Code.

§1735.2. Records

(a) For each compounded drug a record shall be made that includes at least the following elements:

(1) The information required of a master formula record.
(2) The date the drug was compounded.
(3) The identity of the pharmacy personnel who compounded the drug.
(4) The identity of the pharmacist reviewing the final product.
(5) The quantity of each component used compounding a drug.
(6) The supplier and lot number of each component.
(7) The equipment used compounding a drug.

CPhA: More detail is needed on what "equipment used" really should include.

(8) The internal reference (lot) number.
(9) The expiration date of the final drug.

Dan Wills: **Expiration date** should be changed to *beyond use date*. It will then match 1735.1 (e) as well as be current with emerging industry vocabulary. Expiration dates are used for manufactured drugs and beyond use dates for compounds. (This would also be a reason to add potency in the paragraph above.

(10) The quantity or amount of drug product compounded.

(b) Pharmacies must maintain records of the acquisition, storage, and proper destruction of chemicals, drug products, and components used in compounding.

(c) The chemicals, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall maintain certificates of purity or analysis for components, chemicals, or drug products used in compounding. Certificates of purity or analysis are not required for drugs used in compounding that are approved by the Food and Drug Administration.

Dan Wills: "The pharmacy shall maintain certificates of purity or analysis for **components, chemicals, or drug products used in compounding**." Certificates of analysis cannot be obtained for sugar purchased at the grocery store. Somebody came up with a good alternative wording a couple years ago, but I can't remember what it was. Was it limited to active ingredients? Also, I would like to be able to have the C of A's accessible by computer. PCCA has them all online to be checked. We are told by OSHA that this method is OK for MSDS sheets. Let's make it OK for C of A's.

"Certificates of purity or analysis are not required for *Food and Drug Administration approved manufactured* drugs used in compounding." An example of the difference in wording is that we use ketoprofen powder which is an FDA approved drug from an FDA approved facility. As the sentence currently reads, we may not be required to maintain a C of A for that. I believe this change meets the spirit of what was desired.

CPHA: "Certificates of purity or analysis are not required for components used in compounding that are approved by the Federal Food and Drug Administration." An important consideration here is to either include or exempt foods, food colorings, flavorings or other components that are not subject to the drug approval process.

(d) Pharmacies must prepare, maintain, and retain all records required by this article in the pharmacy in a readily retrievable form for a period of three years from the date the record was created.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005 Business and Professions Code.

§1735.3. Labeling

(a) In addition to labeling information required under Business and Professions Code Section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active component(s).

(b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.

(c) Drugs compounded into unit-dose containers shall be labeled with the name of the active component, concentration or strength, volume or weight, and an expiration date.

Dan Wills: Again change **expiration date** to *beyond use date.*

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4076, Business and Professions Code.

§1735.4. Policies and Procedures

(a) Pharmacies must maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures for the pharmacy.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge.

(c) Provisions to notify the staff assigned compounding duties of any changes in the policy and procedure manual must also be included.

(d) The policy and procedure manual shall include written documentation of a plan for the recall of dispensed compounded products where subsequent verification demonstrates the potential for adverse effects with continued use of the compounded drug.

(e) Written processes used to maintain, store, calibrate, clean/disinfect equipment used in compounding drug shall be contained in the policy and procedure manual and shall be incorporated as part of the staff training and competency evaluation process.

Dan Wills: Written processes **used** to maintain, ..." change to "Written processes *outlining how* to maintain, ..." Written processes aren't the too used to do the maintaining, etc.

(f) The pharmacist-in-charge shall establish policies and procedures to ensure that compounded drugs have the strength indicated by the label.

CPHA: Pharmacies must maintain a readily retrievable policy and procedure manual for compounding activities that includes at least:

(a) Procurement procedures for components used in compounding;
(b) Methods for the determining formulations and compounding processes for drug products;
(c) Requirements for general cleaning and maintenance of facilities and equipment;
(d) Standard operating procedures for the pharmacy;
(e) Procedures for recalling dispensed compounded products;
(f) Procedures for maintenance, storage, calibration, cleaning and disinfecting equipment used in compounding drug products;
(g) Steps used to ensure that compounded drugs products have their labeled strength, consistent with standards for the profession;
(h) Methods to notify the staff assigned to compounding dutes of any changes in the policy and procedure manual.

The policy and procedure manual shall be reviewed annually by the pharmacist-in-charge.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005 and 4113, Business and Professions Code.

§1735.5. Facilities and Equipment

(a) Pharmacies shall provide written documentation of facilities and equipment necessary for the safe and accurate compounding of a drug, to also include, where applicable, certification of the facility/equipment.

Dan Wills: "Pharmacies shall provide **written documentation of facilities and equipment** necessary for the safe..." How do you document a facility? Perhaps it would be better stated, "*Where applicable, pharmacies shall provide documentation that the facilities and equipment will function as* necessary for the safe..."

(b) Equipment shall be stored, used, and maintained in accordance with manufacturers' specifications.

(c) Equipment used in compounding drug products shall be calibrated prior to use to ensure accuracy. Documentation of calibration shall be recorded in writing.

Dan Wills: "Documentation of calibration shall be recorded *and maintained.*" Some people like to maintain these records on a computer instead of **in writing**.

CPhA: (a) Requires clarification. The use of the word "documentation" here is confusing. What needs to be documented or what sort of documentation is needed?

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1735.6. Training of Staff, Patient and Caregiver

(a) Pharmacies shall maintain written documentation that pharmacy personnel have the skills and training required to correctly perform their assigned responsibilities relating to compounding.

(b) The training of pharmacy personnel shall be documented and retained as part of an on-going competency evaluation process for pharmacy personnel involved in compounding.

CPHA: Add at the end of subsection (b): The ongoing training and competency evaluation process shall include the procedures for maintenance, storage, calibration, cleaning and disinfecting of equipment used in compounding drug products.

(c) Pharmacy personnel assigned compounding duties shall demonstrate knowledge about the processes and procedures used to compound drug drugs prior to compounding any drug.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

§1735.7. Quality Assurance

(a) Pharmacies shall provide written documentation of the development of and adherence to a quality assurance plan.

Dan Wills: Pharmacies shall provide documentation of *the* adherence to a quality assurance plan." Do we really need to document **the development** of one?

CPhA: (a) eliminate "the development of and" There's no need to provide documentation of the development of a QA plan. The existence of one is sufficient documentation of whatever is intended here.

(b) The quality assurance plan shall include verification, monitoring, and review of the adequacy of the compounding process and shall include documentation of that review by the assigned personnel to demonstrate the compounded drug meets the specified criteria of strength and quality.

(c) As part of the quality assurance plan, all qualitative/quantitative analysis reports for compounded drug drugs shall be retained and collated with the compounding record and master formula.

(d) The quality assurance plan shall also include a written process that describes and documents the action taken when a compounded drug fails to meet the minimum standards for quality, strength and integrity.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

NACDS
NATIONAL ASSOCIATION OF CHAIN DRUG STORES

March 2, 2007

Ms. Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd. N219
Sacramento, CA 95834

Dear Ms. Herold:

Re: Article 4.5 General Compounding

On behalf of the approximately 2,914 chain pharmacies that operate in the state of California, the National Association of Chain Drug Stores (NACDS) thanks the California Board of Pharmacy ("Board") for the opportunity to comment on the proposed rule amendments affecting the compounding of prescription drugs.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

We are concerned that many of the proposed requirements would prevent most pharmacies from engaging in "nonsterile basic" compounding. The Pharmacy Compounding Accreditation Board (PCAB) defines "nonsterile basic" compounding as "compounding which involves the preparation of a formulation containing two or more nonsterile commercially available products employing basic pharmacy training skill sets, as well as, defined policy, procedures and processes necessary to ensure quality and consistency of the completed compounded preparation."[1] We believe that many of the proposed rules' requirements would place unnecessary burdens on pharmacies that engage only in this type of compounding on an occasional basis, pursuant to a prescription. Consequently, these pharmacies would no longer engage in compounding of any products for patients. We fear that patients' health and well-being may be negatively impacted if their local pharmacies are not able to provide nonsterile, basic compounded products.

We ask the Board to distinguish "nonsterile basic" compounding from other types of compounding, as defined by PCAB. We believe that many of the requirements for complex and sterile compounding are not appropriate for nonsterile basic compounding. As recognized by PCAB's definition, such compounding includes nonsterile products that are already commercially available, and requires only basic pharmacy training skill sets. With this in mind, we ask the Board to reconsider the following rules as they would apply to nonsterile basic compounding:

- 1735.1(b) – We believe that it would be unnecessarily burdensome for pharmacies to have to create a written master formula to engage in common nonsterile basic compounding, such as combining two commercially-available topical

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[1] *PCAB Standards with Compliance Indicators*, p. 27, located at www.pcab.info.

preparations, mixing together commercially-available liquids, or mixing a commercially-available injectable drug into a commercially-available topical preparation, all pursuant to a specific prescription order. For these products, the formula is the prescription order. We ask the Board not to require a written master formula for nonsterile basic compounding, or in the alternative, to allow such information to be recorded electronically.

- 1735.1(h) – For many of the same reasons, we believe the self-assessment requirement is not appropriate for nonsterile basic compounding. Since by its definition this type of compounding employs only basic pharmacy training skill sets, any licensed pharmacist should be able to engage in this type of compounding without additional oversight by a pharmacist-in-charge.
- 1735.4 – We ask the Board to clarify that the policy and procedure manual may recognize that many of the policies and procedures that apply to complex and sterile compounding would not apply to nonsterile basic compounding, such as procurement procedures, compounding and formulation methodologies, and quantitative/qualitative analysis reports.
- 1735.6 – We ask the Board to reconsider for nonsterile basic compounding the requirement of written documentation that pharmacy personnel have the skills and training required to correctly perform their assigned responsibilities relating to compounding. Nonsterile basic compounding employs basic pharmacy skill sets that any licensed pharmacist should readily possess. Similarly, we ask the Board amend the ongoing competency requirement such that pharmacists that engage only in nonsterile basic compounding would be encouraged to attend continuing education courses on this type of compounding, and that no additional ongoing competency would be required.

We ask the Board to consider our concerns so that all pharmacies may continue to engage in nonsterile basic compounding. We fear that if the proposed rules were adopted as currently written, most pharmacies would choose not to engage in any compounding due to the unnecessarily burdensome nature of the rules as they relate to nonsterile basic compounded products. We understand the Board must consider all factors that might affect public health and safety; we urge the Board to consider the difficulty consumers would face in obtaining nonsterile, basic, compounded products as a factor in your deliberation.

Under proposed Section 1735.1(a), the Board would require a dispensing pharmacist to establish a professional relationship with both a prescriber and a patient prior to compounding a drug. We ask that the Board require the dispensing pharmacist to establish a professional relationship only with the prescriber prior to compounding the drug, and with the patient prior to dispensing the compounded drug.

Some prescribers frequently prescribe the same compounded drug or drugs over time. For these prescribers, it is helpful for the prescriber, pharmacist, and patients for the pharmacist to be able to compound such drugs ahead of time based upon the prescriber's

routine prescribing habits. This way compounded products can be readily available for patients.

Compounding drugs can be a time-consuming process. Pharmacists may not have time to compound drugs during busy days, and may need to delay compounding a drug to another day, or perhaps over a weekend, when prescription volumes are lower. Allowing a pharmacist to compound ahead of time based on routine prescribing habits would allow pharmacists to plan ahead, rather than have to make patients wait hours or days for their compounded drugs. With demands on pharmacies ever increasing, pharmacies find it helpful to have available for patients compounded drugs that are commonly prescribed.

Under proposed rule 1735.2(b), we ask the Board to allow pharmacies to maintain in readily-retrievable centralized records information on the acquisition, storage, and proper destruction of chemicals, drugs, and components used in compounding. Many pharmacies presently maintain this information in this manner, and we ask the Board to clarify that pharmacies may continue to do so.

Finally, we ask the Board to clarify that adding a flavoring agent to a commercially-available product is not considered "compounding." Many patients prefer to have the flavor of an oral liquid medication changed to better suit their tastes; pharmacists oblige, recognizing that doing so will increase patient adherence to their medication therapy. Please clarify that merely changing the flavor of a medication is not considered "compounding," as doing so does not change the therapeutic effect of the medication and can positively affect patient adherence. Considering this service to be compounding would only act as a deterrent for pharmacists to provide this service, as having to comply with compounding requirements would be unnecessary burdens.

We thank the Board for considering our comments. Please do not hesitate to contact us if we can further assist you.

Sincerely,

Kevin Nicholson, R.Ph., J.D.
Vice President
Pharmacy Regulatory Affairs

Dan Wills
<danwills1@yahoo.com>
02/28/2007 06:31 PM

To Virginia_Herold@dca.ca.gov
cc
bcc
Subject compounding

Sorry, my regular e-mail is down. I don't have access to the other comments. Here is what I have. Thanks, Dan

Here are some beginning comments and concerns. I can't find a word document of this, so I can't just make changes on the document itself. This needs to be concluded Now so they can use it at the licensing committee in 2 weeks. Do any of you have ideas or a change of thoughts before this gets turned in?

1735 I notice that flavoring was taken out. I remember that being done since many of the chains are now flavoring. However, I have also heard stories by pharmacies that have had to fix problems associated with flavoring of meds by non-compounders. Most of the time it has to do with interactions of the flavoring agent or actually making the flavor worse. Do we want to re-look at this?

1735 (a) "Compounding" means any of the following activities occurring in a pharmacy pursuant to a prescription *or in anticipation of a prescription based on past history* : I can't find anything that allows us to make preparations in a larger batch. This is sometimes needed for accuracy and safety, particularly when there is a very small dosage or therapeutic range. Business principles will stop people from making more than they will reasonably use. That would only incur waste. By putting past history in it, there would be an adjustment for the size of the operation. If a pharmacy only does one of these a week, they probably shouldn't make very much. If the demand is high however, and it can be proven historically, then a larger batch would make more sense. It also eliminates a regulatory punishment for success.

In the last line of the paragraph, there is a typo; "rectal o topical…"

1735 (b) "…will retain its **effectiveness**…" Aren't there cases where therapeutically a drug will become less effective even though it is still full strength? I would suggest changing to "…will retain it its *potency* …"

1735 (c) "…drug is free of **any** contaminants…" Should be changed to "*harmful levels* " or something similar. The air we breath has 100,000 contaminants in a cubic foot. Even sterile compounding laws allow us to have endotoxins as long as they are non-pyrogenic. Making something free of any contaminants is impossible.

1735.1 (a) "...pharmacist shall establish a **professional relationship,** *as evidenced by a valid prescription,* with the prescriber and patient." Does a prescription constitute a professional relationship? If not, this would be difficult to define. Would it mean a phone call? A personal visit? Taking them out to dinner? If a prescription is not good enough, we are being held to a higher standard than other pharmacists. When a prescription is brought in by the patient, or transmitted from a doctor, there is no question of a relationship. There is just an implied relationship and it is just filled. Also, this wording puts the burden on the pharmacist to create the relationship. What if a veterinarian who we have not met, calls us and prescribes for Fluffy who we have also never had an interaction with? What would need to be done? If anything more than a valid prescription is required to "establish a relationship," we will hurt many patients in rural areas who do not have immediate access to the pharmacy.

1735.1 (b) (4) "...quality reviews at each *appropriate* step in the preparation." This allows for professional judgment.

1731.1 (e) ".. supported by **stability studies**..." Can we change this to "...supported by stability *and/* or *potency studies* ...?" Recently there has been a lot of talk about this subject on the IJPC network as well as with testing labs. A stability study will costs thousands of dollars to find out all the degradants (sp?) in the medicine. Currently when we send something in for testing, we will check for potency and if appropriate sterility and pyrogenicity. I know that stability studies would be better, but if a capsule we make still tests out to be just as potent in one year as on day one, why not put that on the container? Especially if the bulk powder doesn't expire for 10 years. Stability studies are used in manufacturing. They are not standard procedure in compounding. We need to start gathering stability studies from the entire industry, but That will be a slow process. If potency is good at day one, why not OK at day 365?
We have a doctor that invented a vitamin B5/B6 cream. After a couple of weeks it oxidizes. He has had it tested, and found it to be just as potent as far as the vitamin is concerned and it still works for his patients. However, the drug is not stable, because of the oxidization. Here is a case where it would fail stability, yet be therapeutically effective. Isn't that the real issue? By adding potency to the regulations we eliminate the "pull it out of the air" approach, can have some scientific basis for a date, yet allow for professional judgment. Isn't that what you paid the big bucks at school for?

1735.2 (a) (9) **Expiration date** should be changed to *beyond use date* . It will then match 1735.1 (e) as well as be current with emerging industry vocabulary. Expiration dates are used for manufactured drugs and beyond use dates for compounds. (This would also be a reason to add potency in the paragraph above.

1735.2 (c) "The pharmacy shall maintain certificates of purity or analysis for **components, chemicals, or drug products used in compounding**." Certificates of analysis cannot be obtained for sugar purchased at the grocery store. Somebody came up with a good alternative wording a couple years ago, but I can't remember what it was. Was it limited to active ingredients? Also, I would like to be able to have the C of A's accessible by computer. PCCA has them all online to be checked. We are told by OSHA that this method is OK for MSDS sheets. Let's make it OK for C of A's.

"Certificates of purity or analysis are not required for *Food and Drug Administration approved manufactured* drugs used in compounding." An example of the difference in wording is that we use ketoprofen powder which is an FDA approved drug from an FDA approved facility. As the sentence currently reads, we may not be required to maintain a C of A for that. I believe this change meets the spirit of what was desired.

1735.3 (c) Again change **expiration date** to *beyond use date.*

1735.4 (e) "Written processes **used** to maintain, ..." change to "Written processes *outlining how* to maintain, ..." Written processes aren't the too used to do the maintaining, etc.

1735.5 (a) "Pharmacies shall provide **written documentation of facilities and equipment** necessary for the safe..." How do you document a facility? Perhaps it would be better stated, " *Where applicable, pharmacies shall provide documentation that the facilities and equipment will function as* necessary for the safe..."

1735.5 (c) "Documentation of calibration shall be recorded *and maintained.* " Some people like to maintain these records on a computer instead of **in writing**.

1735.7 (a) "Pharmacies shall provide documentation of *the* adherence to a quality assurance plan." Do we really need to document **the development** of one?

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Comments on Proposed Compounding Regulations

Comments with General Applicability:

1) The proposed language contains several references to either "expiration date" or "beyond use date." These references should be amended so ~~that only one term~~ is used, which, based on industry usage and trends, we believe should be "beyond use date."
2) There are several sections which require "written" documentation of some sort. These sections should be changed to "readily retrievable" in order to allow records to be kept electronically rather than require retention of paper documents.

Specific sections:
1735 Definitions [later]

§1735.1. Requirements for compounded drug products
(a) belongs in a separate section.
(b)(4) change to: "Quality reviews required at appropriate steps in the preparation of the compounded preparation." Not all steps in the compounding process require qualtiy review.
(e) Eliminate the word "stability" before "studies" in the third line. The expense of a formal "stability study" is not an appropriate requirement; what is needed is some form of study that supports an extended beyond use date for a compounded drug product.

§1735.2 Records
(a)(7) More detail is needed on what "equipment used" really should include.

(c) change last sentence to: "Certificates of purity or analysis are not required for components used in compounding that are approved by the Federal Food and Drug Administration." An important consideration here is to either include or exempt foods, food colorings, flavorings or other components that are not subject to the drug approval process.

1735.4 Policies and Procedures
Change to:
Pharmacies must maintain a readily retrievable policy and procedure manual for compounding activities that includes at least:

(a) Procurement procedures for components used in compounding;
(b) Methods for the determining formulations and compounding processes for drug products;
(c) Requirements for general cleaning and maintenance of facilities and equipment;
(d) Standard operating procedures for the pharmacy;
(e) Procedures for recalling dispensed compounded products;
(f) Procedures for maintenance, storage, calibration, cleaning and disinfecting equipment used in compounding drug products;
(g) Steps used to ensure that compounded drugs products have their labeled strength, consistent with standards for the profession;

(h) Methods to notify the staff assigned to compounding dutes of any changes in the policy and procedure manual.

The policy and procedure manual shall be reviewed annually by the pharmacist-in-charge.

§1735.5 Facilities and Equipment

(a) Requires clarification. The use of the word "documentation" here is confusing. What needs to be documented or what sort of documentation is needed?

§1735.6 Staff

Add at the end of subsection (b): The ongoing training and competency evaluation process shall include the procedures for maintenance, storage, calibration, cleaning and disinfecting of equipment used in compounding drug products.

§1735.7 Quality Assurance

(a) eliminate "the development of and" There's no need to provide documentation of the development of a QA plan. The existence of one is sufficient documentation of whatever is intended here.

Attachment 5

Proposed Federal Legislation Regarding Compounding by Pharmacies

Trouble Brewing for Compound-Mixing Pharmacists

By Rebecca Adams, CQ Staff

Medicine is such a huge high-tech industry that it seems a throwback to the 19th century — or earlier — for pharmacists to hand-mix batches of drugs with a mortar and pestle.

But that is essentially what they are continuing to do, mainly for patients who have allergies or other special needs preventing them from ingesting mass-produced pharmaceutical products. What's more, such pharmacist-prepared treatments get no regulatory approval from the Food and Drug Administration.

That may soon change, however. Big pharmaceutical companies have joined forces with aggrieved families of patients who allege they've been harmed by hand-mixed medicines — known as "compounds" in pharmaceutical argot — to push for the passage of a bill currently being drafted by **Edward M. Kennedy** of Massachusetts, the new Democratic chairman of the Senate Health, Education, Labor and Pensions Committee.

Kennedy's bill would bring compounds under stronger regulation by the FDA and add limits to their distribution. Supporters contend it would stem an increasingly widespread trend in the high-cost pharmaceutical world: Pharmacies becoming de facto drug manufacturers, turning out enormous batches of medicine that, in some cases, have proven harmful to patients.

Kennedy is working on his 24-page draft with two Republicans, **Richard M. Burr** of North Carolina and **Pat Roberts** of Kansas. On the other side of the fight are pharmacist groups such as the International Academy of Compounding Pharmacists and the National Community Pharmacists Association, who already fear that the bill will get attached to a measure — considered a "must pass" this year — to extend the system for financing the FDA's pre-market drug approval process.

State pharmacy boards currently oversee the thousands of pharmacies that make compounds. Kennedy's plan would shift primary oversight to Washington.

Nine pharmacy organizations have sent a letter to the senators protesting some of their likely provisions, including a requirement for physicians to document the need for prescribed compounds, new restrictions on the use of injectable compounded medicines in doctors' offices, and mandatory labeling that stipulates that compounds are not prepared in accordance with FDA's manufacturing standards.

"What they're trying to do is insert FDA into the long-established doctor-patient relationship," says **Tony Lee**, director of public policy for the National Community Pharmacists Association, a trade group. "FDA already has strained resources."

Bigger drug manufacturers counter that compound makers are exploiting their regulatory exemption for profit. "They're basically making bulk quantities and selling them to doctors at a discount," says **Eamonn P. Hobbs**, whose company, AngioDynamics, manufactures treatments for varicose veins.

Companies such as AstraZeneca, which makes a drug for asthmatics, are teaming up with an activist group called the Allergy & Asthma Network Mothers of Asthmatics to press for the Kennedy bill. The mothers say that some pharmacies filled prescriptions using store-made compounds without informing parents, exacerbating their children's asthma symptoms.

Bill supporters are in high lobbying mode. The mothers group has created a 12-organization coalition, the Consumer Health Alliance for Safe Medication, supported in part by drug companies and patient groups, and it is already sending blasts of e-mail to it supporters. "If you don't contact your senator TODAY," one reads, "businesses who make a living giving patients potentially harmful medications will make sure this legislation never makes it to a vote!"

The alliance plans to hold a three-day forum in Washington starting April 30 that kicks off with a session including an update on their advocacy campaign. Pharmacists, meanwhile, plan to devote their July fly-in to Capitol Hill to lobbying their side of the issue — and reminding legislators that existing laws and regulations effectively curb abuses.

Drug companies want bright-line language in the bill to stem any pharmacy-based manufacturing of drugs. "When a pharmacy is compounding a product, it should be because there's no commercially available product," says **Marjorie Powell**, senior assistant general counsel for the Pharmaceutical Research and Manufacturers of America. The group also wants to ban compounders from using ingredients withdrawn from commercial medicine uses and to ensure that they work in sterile environments.

A GOP aide, who requested anonymity because the bill has not been introduced, says the challenge is to produce an effective stand-alone bill that balances the competing interests in the fight — and to pass it, if possible, in time for the August recess, without dragging the bigger FDA user-fee legislation into the picture. "We need to make it harder for compounders to sell their products in a mass way," says the aide.

****

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110TH CONGRESS
1ST SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to provide for safe and appropriate compounding of drugs by licensed pharmacists and physicians.

IN THE SENATE OF THE UNITED STATES

introduced the following bill; which was read twice and referred to the Committee on

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for safe and appropriate compounding of drugs by licensed pharmacists and physicians.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Safe Drug Compounding Act of 2007".

SEC. 2. PHARMACY COMPOUNDING.

Section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) is amended to read as follows:

"SEC. 503A. PHARMACY COMPOUNDING.

"(a) DEFINITIONS.—In this section—

"(1) the term 'bulk drug substance' has the meaning given the term in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation);

"(2) the term 'compounding'—

"(A) includes the process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a drug tailored to the needs of an individual patient; and

"(B) does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by a product's manufacturer and other manufacturer directions consistent with that labeling;

"(3) the term 'essentially a copy of a drug approved by the Secretary'—

"(A) includes a drug product for which there is no legitimate medical need for any difference in ingredients, dosage form, route of administration, or strength from the comparable drug approved by the Secretary; and

"(B) does not include a drug product in which there is a change, made for an identified

proved by the Secretary;

"(4) the term 'sterile drug product' means any drug product—

"(A) to be administered parenterally;

"(B) for topical use on or in the eye;

"(C) that is an aqueous-based solution for inhalation; or

"(D) that the Secretary defines by regulation to be a sterile drug product; and

"(5) the term 'valid prescription order' means a prescription order—

"(A) for an identified patient; and

"(B) completed by a practitioner authorized by State law to prescribe drugs that is within an established relationship with such patient.

"(b) APPLICATION.—

"(1) APPLICABILITY OF ACT TO COMPOUNDED DRUG PRODUCTS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), this Act shall apply to compounded drug products.

"(B) EXEMPTION FOR CERTAIN DRUGS.—Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a compounded drug product if, with respect to such compounded drug product, the requirements of this section are met.

"(C) NO EXEMPTION FOR NON-COMPLIANT DRUGS.—Sections 501(a)(2)(B), 502(f)(1), and 505 shall apply to a compounded drug product if, with respect to such compounded drug product, the requirements of this section are not met.

"(2) APPLICATION OF SECTION.—This section shall not apply to—

"(A) compounded positron emission tomography drugs, as defined in section 201(ii); or

"(B) radiopharmaceuticals.

"(c) COMPOUNDING.—

"(1) IN GENERAL.—Drug products that are compounded shall be compounded only in accordance with this paragraph as follows:

"(A) COMPOUNDING BY LICENSED PHARMACIST OR LICENSED PHYSICIAN.—A drug product shall be compounded by—

"(i) a licensed pharmacist in a State licensed pharmacy or a Federal facility; or

"(ii) a licensed physician.

"(B) COMPOUNDING ON VALID PRESCRIPTION ORDER OR ON HISTORY OF VALID PRESCRIPTION ORDERS.—

"(i) IN GENERAL.—A drug product shall be compounded—

"(I) for an identified individual patient based on—

"(aa) the receipt by the compounding pharmacist or physician of a valid prescription order that indicates that a compounded drug product is needed by the identified individual patient; or

"(bb) a notation, made by the compounding pharmacist or physician based on a conversation between the compounding pharmacist or physician and the pre-

scribing practitioner, on a valid prescription order that the prescribing practitioner has determined that a compounded drug product is needed by the identified individual patient, subject to clause (ii); or

"(II) in limited quantities before the receipt of such valid prescription orders for such individual patients when based on a history of the compounding pharmacist or physician receiving such valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

"(aa) the compounding pharmacist or physician; and

"(bb)(AA) such individual patients for whom such prescription orders will be provided; or

"(BB) the practitioners who will write such prescription orders.

"(ii) NOTATION.—A compounding pharmacist or physician may make a notation as described in clause (i)(I)(bb), if the drug approved by the Secretary that the valid prescription order indicates should be dispensed to the individual patient is not immediately available for dispensing to the patient, either because the drug is not stocked or is in short supply, in which case the compounding pharmacist or physician may dispense a quantity of a compounded drug product only in a quantity necessary to ensure the health and safety of the patient through the time reasonably expected to be required to acquire the drug approved by the Secretary.

"(C) DISPENSING BY COMPOUNDING PHARMACIST OR PHYSICIAN.—A compounded drug product shall be dispensed to the individual patient for which the drug product was prescribed—

"(i) on receipt of the valid prescription order described in subparagraph (B)(i)(I); and

"(ii) by the compounding pharmacist or physician, unless the patient is an inpatient at a health care facility, such as a hospital.

"(D) BULK DRUG SUBSTANCES.—A drug product shall be compounded using bulk drug substances that—

"(i)(I) are drug substances that are components of drugs approved by the Secretary;

"(II) if the drug substance is not a component of a drug approved by the Secretary, comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or

"(III) if the drug substance is not a component of a drug approved by the Secretary and such a monograph does not exist, appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (e);

"(ii) are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

"(iii) are accompanied by valid certificates of analysis for each bulk drug substance (which certificates shall be maintained for a period of not less than 2 years after the drug product is dispensed or the drug substance is disposed of, whichever is later).

"(E) OTHER INGREDIENTS.—Ingredients (other than bulk drug substances) that are used in the compounding of a drug product shall—

"(i) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists;

"(ii) comply with the standards of the United States Pharmacopoeia chapter on pharmacy compounding; and

"(iii)(I) be listed in the Inactive Ingredient Guide of the Food and Drug Administration as approved in a product with

the same route of administration and within the potency range listed; and

"(II) not be identified as inappropriate for such a drug product on the list published by the Secretary in the Federal Register as provided for in subsection (e)(3).

"(F) STERILE DRUG PRODUCTS.—A sterile drug product shall be compounded—

"(i) solely from ingredients that are—

"(I) sterile; and

"(II) tested and determined by the compounding pharmacist or physician to be free of endotoxins or other filth that may make the drug product injurious to health; and

"(ii) in conformity with—

"(I) standards for sterile compounding established by the Secretary by regulation; or

"(II) if such regulations do not exist, standards of the United States Pharmacopoeia for sterile compounding.

"(G) REQUIRED DISCLOSURES IN LABELING.—

"(i) IN GENERAL.—A compounded drug product shall be dispensed with labeling containing—

"(I) the statement 'This drug was made specifically for you, because your health care provider determined that no FDA-approved product would suit your needs. It must comply with Federal and State pharmacy guidelines for preparing drugs, but is not required to meet the safety, efficacy, or manufacturing standards for FDA-approved drugs. If you have questions about this medication, ask your health care provider.';

"(II) if the drug product is a sterile drug product, the additional statement 'This drug was not prepared using FDA's manufacturing standards for sterile drugs';

"(III) the date on which the drug was compounded;

"(IV) the name of the licensed compounding pharmacist or compounding physician; and

"(V) relevant information from labeling, including from medication guides, required by the Secretary to be provided to patients when a drug approved by the Secretary with an active ingredient used in the compounded drug product is dispensed to patients.

"(ii) NONAPPLICATION.—Clause (i)(II) shall not apply to the labeling of a sterile drug product if the facility in which the sterile drug product is compounded is—

"(I) registered under section 510; and

"(II) found by the Secretary, after an inspection under section 704, to be in compliance with the requirements of section 501(a)(2)(B) for manufacturing sterile drug products.

"(H) REQUIRED DISCLOSURES IN ADVERTISING.—

"(i) REQUIRED STATEMENT FOR DIRECT-TO-CONSUMER ADVERTISING OF A COMPOUNDED DRUG.—Any advertising or promotion directed to consumers of a compounded drug, shall include the following statement that is displayed or stated prominently and conspicuously: 'This drug can be made specifically for you by a pharmacist if your health care provider determines that no FDA-approved product would suit your needs. It must comply with Federal and State pharmacy guidelines for preparing drugs, but is not required to meet safety and efficacy standards for FDA-approved drugs. If you have questions about this medication, ask your health care provider.'.

"(ii) REQUIRED STATEMENT FOR ADVERTISING OF A COMPOUNDED DRUG TO HEALTH CARE PROVIDERS.—Any advertising or promotion directed to health care providers of a compounded drug shall include the following statement that is displayed or stated prominently and conspicuously: 'This drug can be made specifically

for your patient by a pharmacist if you decide that no FDA-approved product would suit that patient's needs. Such compounded drugs must comply with Federal and State pharmacy guidelines but are not required to meet the safety and efficacy standards for FDA-approved drugs.'.

"(iii) REQUIRED STATEMENT FOR ADVERTISING OF COMPOUNDING SERVICES.—Any advertising or promotion of more than 1 compounded drug or of compounding services by a pharmacist or physician, shall include the following statement that is displayed or stated prominently and conspicuously: 'Compounded drugs can be made specifically for a patient when the patient's health care provider determines that no FDA-approved product meets the patient's needs. Such compounded drugs must comply with Federal and State pharmacy guidelines for preparing drugs, but are not required to meet safety and efficacy standards for FDA-approved drugs. Patients with questions about such medications should ask their health care providers.'.

"(iv) REQUIRED STATEMENT WITH RESPECT TO STERILE DRUG PRODUCTS.—Any advertising or promotion of a compounded drug that is, or of compounding services for, a sterile drug product, shall include, in addition to statements otherwise required under this subsection, the following statement that is displayed or stated prominently and conspicuously: 'The sterile drugs or sterile compounding drug services offered in this promotion are not prepared or performed using FDA's manufacturing standards for sterile drugs.'.

"(v) NONAPPLICATION.—Clause (iv) shall not apply to advertising or promotion for a compounded sterile drug product, or for compounding services for sterile drug products, if the facility in which the drug product is compounded, or in which the compounding occurs, is—

"(I) registered under section 510; and

"(II) found by the Secretary, after an inspection under section 704, to be in compliance with the require-

ments of section 501(a)(2)(B) for manufacturing sterile drug products.

"(2) DRUG PRODUCTS THAT SHALL NOT BE COMPOUNDED.—A drug product shall not be compounded if the drug product is—

"(A) essentially a copy of a drug approved by the Secretary, except in a quantity necessary to ensure the health and safety of a patient through the time reasonably expected to be required to acquire the drug approved by the Secretary;

"(B) a drug that appears on the list published by the Secretary in the Federal Register, and published in section 216.24 of title 21, Code of Federal Regulations (or any successor regulation), of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; or

"(C) identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product.

"(d) SEMI-ANNUAL REPORTS FOR DRUGS DISTRIBUTED OUTSIDE STATE IN WHICH COMPOUNDED.—

"(1) IN GENERAL.—A pharmacist or physician who compounds drugs shall submit to the Secretary a semi-annual report providing, for each distinct compounded drug product distributed by the pharmacist or physician outside the State in which such pharmacist or physician compounded the drug product—

"(A) the name of the drug product as ordered on a prescription;

"(B) the generic names of all ingredients, and the chemical names of all ingredients without generic names included in the drug product;

"(C) the number of doses of the drug product distributed by such pharmacist or physician outside such State;

"(D) the States to which the drug product was distributed;

"(E) the number of doses of the drug product distributed by such pharmacist or physician within the State in which such pharmacist or physician compounded the drug product; and

"(F) all known serious adverse events associated with use of the drug product.

"(2) STATE BOARDS OF PHARMACY AND MEDICINE.—The Secretary shall share the reports described under paragraph (1) with State boards of pharmacy and medicine, as appropriate, and work with such boards to—

"(A) discourage the distribution of inordinate amounts of compounded drug products in interstate commerce; and

"(B) encourage appropriate State investigation of complaints relating to compounded drug products distributed outside such State.

"(e) REGULATIONS AND IMPLEMENTATION.—

"(1) IN GENERAL.—The Secretary shall issue regulations to implement subsections (c)(1)(D)(i)(III), (c)(2)(B), and (c)(2)(C). Before issuing regulations to implement such subsections, the Secretary shall convene and consult an advisory committee on compounding. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, consumer organizations, and other experts selected by the Secretary.

"(2) LIMITING COMPOUNDING.—The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (c)(1)(D)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

"(3) COMPOUNDING RESTRICTION LIST.—The Secretary, after providing for not less than 6 months of public review and comment, shall publish in the Federal Register a list of active and inactive ingredients and uses of ingredients that may compromise the safety or efficacy of a compounded drug product, including allergens or other substances that must be absent from some or all compounded drug products, chemicals that should not be used in some or all compounding processes, ingredients that should not be combined, or maximum levels of individual ingredients in a compounded drug product. The Secretary

shall update the list not less often than once every 2 years.

"(4) GUIDANCE ON MEDICAL NEED.—The Secretary, in consultation with physicians, other health care providers licensed to prescribe drugs, and compounding pharmacists, shall develop and issue a guidance document that identifies—

"(A) the types of medical needs that justify the use of a compounded drug, such as—

"(i) the need for a drug without a specified inactive ingredient or without an inactive ingredient from a specified source (such as milk or soy) because the patient is allergic to such ingredient or ingredients from such source and the drug approved by the Secretary contains such an ingredient;

"(ii) the need for a drug in a dosage form, route of administration, or strength that differs from drugs approved by the Secretary; and

"(iii) the need for a drug when there is a shortage of the drug approved by the Secretary; and

"(B) the means by which a licensed prescribing physician or other health care provider can notate such a medical need on a prescription form.

"(5) INORDINATE AMOUNTS.—The Secretary may issue a guidance document to describe the term 'inordinate amounts of compounded drug products in interstate commerce'.

"(6) ELECTRONIC PRESCRIBING.—When developing technical standards for electronic prescribing systems, the Secretary shall develop a standard so that a system certified by the Secretary shall allow a licensed prescribing physician or other health care provider to—

"(A) prescribe a compounded drug;

"(B) indicate the nature of the medical need that requires the use of a compounded drug rather than a drug approved by the Secretary; and

"(C) indicate that the prescribing provider has discussed the risks and benefits of using the compounded drug with the patient.

"(7) MEDICAL NEED EXCEPTION.—

"(A) IN GENERAL.—The Secretary shall by regulation identify circumstances in which med-

ical need justifies an exception from compliance with 1 or more requirements of this section, such as when a bulk drug substance that meets the requirements of subsection (c)(1)(D) or an ingredient other than bulk drug substance that meets the requirements of subsection (c)(1)(E) is not available to compound a drug product.

"(B) NOTIFICATION AND CONFIRMATION.—A regulation promulgated pursuant to subparagraph (A) shall require that, to use an exception—

"(i) the compounding pharmacist or physician notify the prescribing practitioner who completed the valid prescription order indicating that a compounded drug product is needed by the identified patient, of the nature of the exception to be used;

"(ii) the prescribing physician confirm the need for the compounded drug product even given the nature of the exception to be used;

"(iii) the compounding pharmacist or physician make a notation of such confirmation on such prescription order; and

"(iv) such patient be informed, both orally when the drug is dispensed or administered and in the drug label, that the compounded drug product was not compounded in compliance with the normal standards for compounding drugs.".

SEC. 3. CONFORMING AMENDMENTS.

(a) INSPECTION.—Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is amended by adding at the end the following:

"(4) Notwithstanding any other provision of this subsection, the provisions of the third sentence of paragraph (1) shall apply to a retail pharmacy that compounds drug products or dispenses compounded drug products, to ensure compliance with section 503A.".

(b) ADVERTISEMENTS.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by striking "or distributor" each place it appears and inserting "distributor, or compounder".

(c) MODIFICATION OF MEDWATCH FORMS.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall modify the Medwatch mandatory and voluntary forms, and other drug safety surveillance systems, to facilitate

Attachment 6

Proposed Name Change for the CPJE

Board of Pharmacy
2007 Omnibus Bill Proposed Language

Amend Sections 4200 – 4200.2 to read:

4200. Pharmacist License Requirements: Age; Education; Experience; Examination; Proof of Qualifications; Fees

(a) The board may license as a pharmacist any applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2)(A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.

(6) Has passed a written and practical examination given by the board prior to December 31, 2003, or has passed the North American Pharmacist Licensure Examination and the ~~Multi-State Pharmacy Jurisprudence Examination for California~~ California Pharmacist – Patient Communication and Jurisprudence Examination on or after January 1, 2004.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist, shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board, the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

(Amended Stats. 2004, Chapter 695)

4200.1. Retaking Examinations; Limits; Requirements [Repeals 1-1-2010]

(a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the ~~Multi-State Pharmacy Jurisprudence Examination for California~~ California Pharmacist – Patient Communication and Jurisprudence Examination four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the ~~Multi-State Pharmacy Jurisprudence Examination for California~~ California Pharmacist – Patient Communication and Jurisprudence Examination four additional times each if he or she successfully

completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.
(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).
(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.
(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the ~~Multi-State Pharmacy Jurisprudence Examination for California~~ California Pharmacist – Patient Communication and Jurisprudence Examination.
(f) From January 1, 2004, to July 1, ***2008, inclusive, the board shall collect data on the applicants who are admitted to, and take, the licensure examinations required by Section 4200. The board shall report to the Joint Committee on Boards, Commissions, and Consumer Protection before September 1, ***2008, regarding the impact on those applicants of the examination limitations imposed by this section. The report shall include, but not be limited to, the following information:
(1) The number of applicants taking the examination and the number who fail the examination for the fourth time.
(2) The number of applicants who, after failing the examination for the fourth time, complete a pharmacy studies program in California or another state to satisfy the requirements of this section and who apply to take the licensure examination required by Section 4200.
(3) To the extent possible, the school from which the applicant graduated and the school's location and the pass/fail rates on the examination for each school.
(g) This section shall remain in effect only until January 1, ***2010, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ***2010, deletes or extends that date.
(Amended Stats. 2006, Chapter 658)

4200.2. ~~Multi-State Pharmacy Jurisprudence Examination for California~~ California Pharmacist – Patient Communication and Jurisprudence Examination; Required Inclusions

When developing the ~~Multi-State Pharmacy Jurisprudence Examination for California~~ California Pharmacist – Patient Communication and Jurisprudence Examination, the board shall include all of the following:
(a) Examination items to demonstrate the candidate's proficiency in patient communication skills.
(b) Aspects of contemporary standards of practice for pharmacists in California, including, but not limited to, the provision of pharmacist care and the application of clinical knowledge to typical pharmacy practice situations that are not evaluated by the North American Pharmacy Licensure Examination.
(Added Stats. 2003, Chapter 539)

Attachment 7

Establishment of State Protocols for Immunizations by Pharmacists

Amend Section 4052 to read:

4052. Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider

(a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) Furnish emergency contraception drug therapy as authorized by Section 4052.3.

(9) Administer immunizations pursuant to a protocol with a prescriber or pursuant to the Center for Disease Control's National Protocol for Vaccinations.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

(Amended Stats. 2006, Chapter 777)

Pharmacy Immunization Protocol

Pharmacy Name

Authorizing Prescriber Statement for Vaccination

<Pharmacist, RPh> of the *<Pharmacy>*, and other licensed pharmacists employed by the *<Pharmacy>*, pharmacy students of the *<Pharmacy>*, acting as delegates for *<Physician>*, M.D. according to and in compliance with Article 3 of the Business and Professional Code 4052.(a).(4).(C) and B&P code 4052.(a).(5).(A).(iii) of the California Pharmacy Scope of Practice section, will independently determine the need for and administer vaccinations and epinephrine, on the premises of the USC Campus Pharmacies, or a suitable alternate location as authorized under Appendix A, and for a fee.

Qualifications of Persons Administering Vaccine

1. CPR certified (BLS) – American Red Cross or American Heart Association or equivalent
2. Certificate of completion of an appropriate immunization program (see Appendix B)

Vaccine(s) to be administered (see Appendix C)

- Influenza (IM and Intranasal)
- Tetanus-diphtheria (Td)
- Tetanus-diphtheria-pertussis (Tdap)
- Pneumococcal (PPV23 adult)
- MMR (for adults)
- HPV
- Meningococcal (MCV4 and MPSV4)
- Varicella Zoster
- Herpes Zoster
- Hepatitis B

Policies

1. A standard form will be used to document immunizations and the pharmacy will maintain a patient record of administration, including, but not limited to, patient name, date, vaccine given (manufacturer, lot #, and expiration date), and signature of person administering vaccine (Appendix D)
2. The screening form contained in this protocol will be maintained as documentation (Appendix D)
3. The current Vaccine Information Statement for each vaccine will be discussed and given to each patient
4. Written informed consent will be obtained for each patient prior to vaccination (Appendix D)
5. The pharmacist will notify the patient's primary care provider of immunization when contact information is available (see Appendix E).
6. All supplies needed for vaccination and vaccine adverse event management as detailed in this protocol will be available and not expired.
7. Authorizing prescriber will be periodically notified of vaccinated patients

Emergencies

Authorize use of the Pharmacy Procedure and Standing Orders for Management of Allergic or Anaphylactic Reactions for emergencies (Appendix F)

Physician Authorization:

Physician Name: *Physician, M.D.* Affiliation (Clinic): _____

Phone: _____ Fax: _____ Pager/Mobile: _____

Physician CA license number: _____ Physician DEA number: _____

_____ _____

Date *<Physician>*, MD

Principle Authorized Pharmacist

_____ _____

Date *<Pharmacist, RPh>*

This authorization will be in effect for 2 years unless rescinded earlier in writing by either party. Any changes in the protocol must be agreed upon by both parties.

APPENDIX A. Alternate Location Request for Vaccine Administration

The pharmacists and intern pharmacists authorized under this protocol may provide vaccination services at the following location in California for the time period specified. All provisions under the policy, procedure and protocol shall remain in effect. Cold chain for storage and subsequent administration of vaccines shall be maintained.

Location and/or Name of Event:_____

Address:_____

Date(s):_____

Signature:

_____ **Date** _____

<Physician> , M.D.

APPENDIX B. Immunization Training

Certificate of completion of an appropriate immunization-training program that includes the *current guidelines and recommendations of the Advisory Committee on Immunization Practices* and uses the core curriculum of the CDC (Epidemiology and Prevention of Vaccine-Preventable Diseases). An appropriate training program shall include, at a minimum, instruction on how to:

A. Identify persons eligible for vaccination based on current ACIP guidelines. (Factors taken into consideration will include age, vaccination status (e.g., persons previously unvaccinated or due for vaccination according to the recommended schedule), or the presence of a medical condition that puts them at high risk, etc.).

B. Screen patients for contraindications and precautions to vaccination (e.g.. severe illness, previous allergic reaction, egg allergy, etc.).

C. Provide adequate information to patients or their guardians regarding the risks for and benefits of a vaccine and documenting the delivery of that information. (i.e. Distribution/discussion of Vaccination Information Statements as required by law).

D. Administer vaccines.

E. Monitor patients for adverse events.

F. Manage anaphylactic reactions according to protocol

G. Report adverse outcomes to the Vaccine Adverse Events Reporting System (VAERS).

H. Record administration of a vaccine(s)

I. Provide documentation of vaccine administration to patients and whenever possible, their primary-care providers.

J. Follow Universal Precautions and Infection Control and pertinent OSHA regulations (i.e. for Blood Bourne Pathogens).

Appendix C. Criteria for Patients to Receive Vaccine

Standing Orders for Administering Hepatitis B Vaccine to Adults

Purpose: To reduce morbidity and mortality from hepatitis B virus (HBV) infection by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses may vaccinate patients who meet the criteria below.

Procedure:

1. Identify adults in need of hepatitis B vaccination based on the following criteria:
   a. Persons less than 19 years of age who have not received the vaccine
   b. Age 19 years or older meeting any of the following criteria:
      - having had more than one sex partner in the previous 6 months, a recently acquired sexually transmitted disease, or recent treatment for a sexually transmitted disease
      - male who has had sex with males
      - injection drug user
      - sex partner or household member of a person who is chronically infected with HBV (including an HBsAg-positive adopted child)
      - at occupational risk of infection through exposure to blood or blood-contaminated body fluid (e.g., health care worker, public safety worker, trainee in a health professional or allied health school)
      - client or staff of an institution for the developmentally disabled
      - hemodialysis patient or patient with early renal failure (who will become a dialysis patient)
      - receiving clotting-factor concentrate
      - planning to travel to or live in a high endemic area of the world for more than 6 months and will have close contact with the local population; also short-term travelers who are likely to have contact with blood (e.g., in a medical setting) or sexual contact with residents of areas with high or intermediate levels of endemic disease
      - housed in a long-term correctional facility
2. Screen all patients for contraindications and precautions to hepatitis B vaccine:
   a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of hepatitis B vaccine or to a hepatitis B vaccine component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf
   b. **Precautions:** a moderate or severe acute illness with or without fever
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speakers with the VIS in their native language if available; these can be found at www.immunize.org/vis
4. For persons 20 years of age or older, administer 1.0 mL hepatitis B vaccine IM (22–25g, 1–1½" needle) in the deltoid muscle. For persons 19 years of age or younger, administer 0.5 mL hepatitis B vaccine IM (22–25g, 1–1½" needle) in the deltoid muscle.
5. Provide subsequent doses of hepatitis B vaccine to complete each patient's 3-dose schedule by observing a minimum interval of 4 weeks between the first and second doses, 8 weeks between the second and third doses, and at least 4 months between the first and third doses.
6. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to hepatitis B vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or by calling (800) 822-7967. VAERS report forms are available at www.vaers.org

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

www.immunize.org/catg.d/p3076.pdf • Item #P3076 (12/03)

Herpes Zoster (HZ Shingles) vaccine

Purpose: To reduce morbidity and mortality from herpes zoster shingles infection by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure:

1. Identify adults in need of herpes zoster shingle vaccination based on meeting the following criteria:
   Any adult 60 years of age or older who has had a case of chicken-pox or received the chicken-pox vaccine previously

2. Screen all patients for contraindications and precautions to shingles vaccine:
   a. **Contraindications:**
   - Are < 60 years of age
   - Serious life-threatening allergic reaction to gelatin, the antibiotic neomycin, or any other component of the HZ shingles vaccine. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf
   - Pregnant now, or may become pregnant with in three months of receiving the shingles vaccine
   - History of primary or acquired immune deficiency including HIV/AIDS, leukemia, lymphomas of any type, and other malignant neoplasms affecting the bone marrow or lymphatic system
   - Are on immune suppressive therapy including high dose corticosteroids
   - Have active untreated tuberculosis

   b. **Possible adverse reactions:** redness, pain, swelling, itching, warmth, bruising at the injection site, and headache.

3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record of office log, the publication date of the VIS and the date it was given to the patient. Provide on-English speakers with the VIS in their native language if available; these can be found at www.immunize.org/vis

4. Administer 0.65mL of Zostavax given SC (23-25g, 5/8-3/4" needle) for 1 dose only.

5. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal Immunization record card:** Record the date of vaccination and the name/location of the administering clinic.

6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.

7. Report all adverse reactions to shingles vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or by calling (800) 822-7967. VAERS report forms are available at www.vaers.org

Updated 11/19/06

Human Papillomavirus Virus (HPV) Vaccine

Purpose: To reduce morbidity and mortality from human papillomavirus (HPV) infection by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure:

1. Identify adolescents and adults in need of HPV vaccination based on meeting any of the following criteria:
   a. females 11-12 years of age (females 9 years of age may also be considered for the vaccine)
   b. females 13-26 years of age who have not been vaccinated previously or who have not completed the full vaccine series

2. Screen all patients for contraindications and precautions to HPV vaccine:
   a. **Contraindications:**
      - Serious life-threatening allergic reaction to yeast, or after receiving a previous dose of HPV vaccine, or any other component of HPV vaccine. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf
      - Avoid use in pregnancy
        -If a woman is found to be pregnant after the series is initiated, the remaining doses should be delayed until after completion of the pregnancy.
        -Merck maintains a Pregnancy Registry to monitor fetal outcomes of pregnant women exposed to Gardasil®. Patients and health care providers are encouraged to report any exposure to Gardasil® during pregnancy by calling 800-986-8999
      - Consider postponing vaccination in persons with moderate or severe illness, with or without fever, until recovery, to minimize potential adverse effects. Low-grade fever itself and mild upper respiratory infection are not generally contraindications to vaccination.
   b. **Precautions:** moderate to severe fever and pain, redness, or tenderness at the injection site

3. Provide all patients with a copy of the most current federal Vaccine information Statement (VIS). You must document, in the patient's medical record of office log, the publication date of the VIS and the date it was given to the patient. Provide on-English speakers with the VIS in their native language if available; these can be found at www.immunize.org/vis

4. For persons 9-26 years of age, administer 0.5mL per dose given IM (22-25g, 1-1 1/2" needle) in the deltoid region of the upper arm or higher anterolateral areas of the thigh.

5. Provide subsequent doses of HPV vaccine to complete each patient's 3 dose schedule by observing a minimum interval of 2 months for the second dose, and 6 months for the third dose.

6. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal Immunization record card:** Record the date of vaccination and the name/location of the administering clinic.

7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.

8. Report all adverse reactions to HPV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or by calling (800) 822-7967. VAERS report forms are available at www.vaers.org

Updated 11/19/2006

Influenza Vaccine

Purpose: To reduce morbidity and mortality from influenza by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure:

1. Identify adults in need of influenza vaccination based on meeting any of the following criteria:
   a. Age 50 years or older
   b. Having any of the following conditions:
      - chronic disorder of the pulmonary or cardiovascular system, including asthma
      - chronic metabolic disease (e.g., diabetes), renal dysfunction, hemoglobinopathy, or immunosuppression (e.g., caused by medications, HIV) that has required regular medical follow-up or hospitalization during the preceding year)
      - any condition that compromises respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration (e.g., cognitive dysfunction, spinal cord injury, seizure disorder or other neuromuscular disorder)
      - will be pregnant during the influenza season
   c. Residence in a nursing home or other chronic-care facility that houses persons of any age who have chronic medical conditions
   d. In an occupation or living situation that puts one in proximity to persons at high risk, including
      - a healthcare worker, caregiver, or household member in contact with person(s) at high risk of developing complications from influenza
      - a household contact or out-of-home caretaker of a child age 0–59 months
   e. Wish to reduce the likelihood of becoming ill with influenza
2. Screen all patients for contraindications and precautions to influenza vaccine:
   a. **Contraindications:** serious reaction (e.g., anaphylaxis) after ingesting eggs or after receiving a previous dose of influenza vaccine or an influenza vaccine component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf. Do not give live attenuated influenza vaccine (LAIV) to pregnant women, immunosuppressed persons, or persons who have a history of Guillain-Barré syndrome. Use of inactivated influenza vaccine is preferred over LAIV for close contacts of severely immunosuppressed persons during periods when the immunocompromised person requires a protective environment.
   b. **Precautions:** moderate or severe acute illness with or without fever
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Administer 0.5 mL of injectable trivalent inactivated influenza vaccine (TIV) IM (22–25g, 1–1½" needle) in the deltoid muscle. Alternatively, healthy persons ages 5–49 years without contraindications may be given 0.5 mL of intranasal LAIV; 0.25 mL is sprayed into each nostril while the patient is in an upright position.
5. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
7. Report all adverse reactions to influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

Measles, Mumps, & Rubella Vaccine

Purpose: To reduce morbidity and mortality from measles, mumps, and rubella by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure

1. Identify adults in need of initial vaccination against measles, mumps, or rubella who were born in 1957 or later with no history of receipt of live, measles-, mumps-, and/or rubella-containing vaccine given at 12 months of age or older or other acceptable evidence of immunity (e.g., laboratory evidence). Combination MMR vaccine is recommended if one or more component is indicated.
2. Identify adults born in 1957 or later in need of a second dose of measles, mumps, and rubella (MMR) vaccine who are either planning to travel internationally, a student in a college, university, technical or vocational school, or a health care worker.
3. Screen all patients for contraindications and precautions to measles, mumps, and rubella (MMR) vaccine:
   a. **Contraindications:**
      - a history of a serious reaction (e.g., anaphylaxis) after a previous dose of MMR vaccine or to an MMR vaccine component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf
      - pregnant now or may become pregnant within 1 month
      - known severe immunodeficiency (e.g., hematologic and solid tumors; congenital immunodeficiency; long-term immunosuppressive therapy, or severely symptomatic HIV infection)
   b. **Precautions:**
      - recent (<11 months) receipt of antibody-containing blood product (specific interval depends on product)
      - history of thrombocytopenia or thrombocytopenic purpura
      - moderate or severe acute illness with or without fever
4. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language; these can be found at www.immunize.org/vis
5. Administer 0.5 mL MMR vaccine SC (23–25g, 5/8–3/4" needle) in the posterolateral section of the upper arm.
6. For adults in need of second doses of MMR, observe a minimum interval of 4 weeks between the first and second doses.
7. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
8. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
9. Report all adverse reactions to MMR vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or (800) 822-7967. VAERS report forms are available at www.vaers.org

This policy and procedure shall remain in effect for all patients of the_____ clinic until rescinded or until _____ (date).

Medical Director's signature: _____ Effective date: _____

www.immunize.org/catg.d/p3079pdf • Item #P3079 (12/03)

Meningococcal Vaccine

Purpose: To reduce morbidity and mortality from meningococcal disease by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure

1. Identify adults in need of vaccination against meningococcal disease based on any of the following criteria:
   a. anticipated college enrollment, particularly anticipated residence in an on-campus dormitory
   b. anticipated travel to a country in the "meningitis belt" of sub-Saharan Africa or other location of epidemic meningococcal disease, particularly if contact with the local population will be prolonged
   c. anticipated travel to Mecca, Saudi Arabia, for the annual Hajj
   d. diagnosis of a damaged spleen; splenectomy
   e. diagnosis of terminal complement component deficiency (an immune system disorder)
   f. employment as a microbiologist with routine exposure to isolates of *N. meningitidis*
   g. military recruits
   h. any other adult wishing to decrease their risk for meningococcal disease
   i. age 55 years or younger with history of receiving **meningococcal polysaccharide vaccine (MPSV4)** at least 5 years earlier and with continued risk for infection (e.g., living in epidemic disease areas).
2. Screen all patients for contraindications and precautions to meningococcal vaccine:
   a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of meningococcal vaccine or to a meningococcal vaccine component, including diphtheria toxoid for **meningococcal conjugate vaccine (MCV4)**. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf.
   b. **Precautions:** moderate or severe acute illness with or without fever
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Although not required by federal law, it is prudent to document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. For adults ages 55 years and younger, administer 0.5 mL MCV4 via the intramuscular route (22–25g, 1–1½" needle) in the deltoid muscle. If MCV4 is unavailable, MPSV4 is an acceptable alternative, although it must be given subcutaneously. For adults older than age 55 years, administer 0.5 mL MPSV4 via the subcutaneous route (23–25g, ⅝" needle) in the posterolateral fat of the upper arm.
5. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
7. Report all adverse reactions to meningococcal vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

Pneumococcal Vaccine - Adults

Purpose: To reduce morbidity and mortality from pneumococcal disease by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure

1. Identify adults in need of vaccination with pneumococcal polysaccharide vaccine (PPV) based on the following criteria:
   a. Age 65 years or older with no or unknown history of prior receipt of PPV
   b. Age 18–64 years with no or unknown history of prior receipt of PPV and any of the following conditions:
      i. chronic cardiovascular disease (e.g., congestive heart failure, cardiomyopathies)
      ii. chronic pulmonary disease (e.g., emphysema or chronic obstructive pulmonary disease [not asthma])
      iii. diabetes mellitus, alcoholism, chronic liver disease (cirrhosis), or cerebrospinal fluid leaks
      iv. functional or anatomic asplenia (e.g., sickle cell disease, splenectomy)
      v. immunosuppressive conditions (e.g., HIV infection, leukemia, congenital immunodeficiency, Hodgkin's disease, lymphoma, multiple myeloma, generalized malignancy)
      vi. immunosuppressive chemotherapy (e.g., alkylating agents, antimetabolites, long-term systemic corticosteroids)
      vii. organ or bone marrow transplantation
      viii. chronic renal failure or nephrotic syndrome
      ix. candidate for or recipient of cochlear implant
2. Identify adults in need of a second and final dose of PPV if five or more years have elapsed since the previous vaccination and the patient is:
   a. Age 65 years or older and received prior PPV vaccination when less than age 65 years
   b. At highest risk for serious pneumococcal infection and/or likely to have a rapid decline in pneumococcal antibody levels (i.e., categories iv.-viii. above)
3. Screen all patients for contraindications and precautions to PPV vaccine.
   a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of PPV or to a vaccine component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf
   b. **Precautions:** a moderate or severe acute illness with or without fever
4. Provide all patients with a copy of the most current federal Vaccine-Information Statement (VIS). Although not required by federal law, it is prudent to document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available. These can be found at www.immunize.org/vis
5. Administer 0.5 mL PPV vaccine either IM (22–25g, 1–2" needle) or SC (23–25g, 5/8–3/4" needle).
6. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to PPV to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or by calling (800) 822-7967. VAERS report forms are available at www.vaers.org

This policy and procedure shall remain in effect for all patients of the_____ clinic until rescinded or until _____ (date).

Medical Director's signature: _____ Effective date: _____

Standing Orders for Administering Tetanus-Diphtheria Toxoids & Pertussis Vaccine (Td/Tdap) to Adults

Purpose: To reduce morbidity and mortality from tetanus, diphtheria, and (where indicated) pertussis by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses may vaccinate adults who meet the criteria below.

Procedure

1. Identify adults in need of vaccination against tetanus, diphtheria, and (where indicated) pertussis based on the following criteria:
   a. lack of documentation of at least 3 doses of tetanus- and diphtheria-containing toxoids
   b. younger than age 65 years with no history of pertussis-containing vaccine given since age 10 years
   c. completion of a 3-dose primary series of tetanus- and diphtheria-containing toxoids with receipt of the last dose being 10 years ago or longer
   d. recent deep and dirty wound (e.g., contaminated with dirt, feces, saliva) and lack of evidence of having received tetanus toxoid-containing vaccine in the previous 5 years
2. Screen all patients for contraindications and precautions to tetanus and diphtheria toxoids (Td) and, if applicable, pertussis vaccine (Tdap):
   a. **Contraindications:**
      - a history of a serious reaction (e.g., anaphylaxis) after a previous dose of Td or to a Td or Tdap component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf.
      - for Tdap only, a history of encephalopathy within 7 days following DTP/DTaP given before age 7 years
   b. **Precautions:**
      - history of Guillain-Barré syndrome within 6 weeks of previous dose of tetanus toxoid-containing vaccine
      - an unstable neurologic condition
      - moderate or severe acute illness with or without fever

      Note: Use of Td or Tdap is not contraindicated in pregnancy. At the provider's discretion, either vaccine may be administered during the 2nd or 3rd trimester.
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Administer 0.5 mL Td (or Tdap, if appropriate) vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle.
5. Provide subsequent doses of Td (a one-time dose of Tdap may be substituted for Td if younger than 65 years) to adults as follows:
   a. to complete the primary 3-dose schedule: observe a minimum interval of 4 weeks between the first and second doses, and 6 months between the second and third doses.
   b. to boost after primary schedule is complete: observe a 10-year interval since previous dose of Td/Tdap; if protection against pertussis is needed, an interval of 5 years is recommended and intervals as short as 2 years or less can be observed for parents and caregivers of infants younger than age 12 months, healthcare workers having direct patient contact, and adults in a pertussis outbreak setting.
   c. In pregnancy, when indicated, give Td or Tdap in 2nd or 3rd trimester. If not administered during pregnancy, give Tdap in immediate postpartum period.
6. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to Td and Tdap vaccines to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

www.immunize.org/catg.d/p3078.pdf • Item #P3078 (9/06)

Pharmacy Name
Address 1
Address 2
Phone#

Patient Name:_____
DOB:_____
Today's Date:_____

VACCINE ADMINISTRATION RECORD, SCREENING and PATIENT CONSENT

		YES	NO
1.	Have you ever had a severe reaction to any vaccine that required medical care?	_____	_____
	If yes, describe:_____		
2.	Do you have any allergies to food, medications, or vaccines?	_____	_____
3.	Are you sick today?	_____	_____
4.	Have you had Guillain-Barre Syndrome, seizure, brain, or nerve problems?	_____	_____
5.	Are you pregnant or planning to become pregnant in the next 3 months?	_____	_____
6.	Are you or anyone in your household being treated with chemotherapy or radiation for cancer, have HIV/AIDS or any immune deficiency disorder?	_____	_____
7.	Do you or anyone in your household take oral prednisone (>20mg/day) or other oral steroids, or anticancer drugs?	_____	_____
8.	Do you have a bleeding disorder or take "blood thinners" like coumadin or heparin?	_____	_____

The following questions will help determine any other indications or contraindications

1. What adult vaccinations has this patient received (vaccine and date)?
   _____
   _____
2. List all Rx and OTC medications this patient is currently taking
   _____
   _____
3. List all current medical conditions
   _____
   _____

INFORMATION ABOUT PERSON TO RECEIVE VACCINE (please print)

NAME last	first	middle initial	SOCIAL SECURITY NUMBER
ADDRESS	CITY	STATE/ZIP	PHONE#
BIRTHDATE	SEX	PHYSICIAN	PHYSICIAN PHONE OR FAX

☐ Yes ☐ No I request to have this information sent to the physician's office specified above

DO NOT WRITE BELOW THIS LINE - For Pharmacy Use Only

VACCINE	LOT #	EXP DATE	MANUFACTURER	DOSE (mL)	ADMINISTRATOR	VIS DATE

Please read the following statements and sign below on the signature line.
I have read or have had explained the information provided about the vaccine I am to receive. I have had a chance to ask questions that were answered to my satisfaction. I believe I understand the benefits and risks of vaccination and ask that the vaccine be given to me or to the person named above for whom I am authorized to make this request.
Medicare, I do hereby authorize the *<Pharmacy>* to release information and request payment. I certify that the information given by me in applying for payment under Medicare is correct. I authorize release of all records to act on this request. I request that payment of authorized benefits be made on my behalf.

X _____ DATE: _____
Signature of person to receive vaccine or person authorized to make the request (parent or guardian)

APPENDIX E

University of Southern California
USC Medical Plaza Pharmacy
1510 San Pablo Street, #144 Los Angeles, CA 90033
(323) 442-8411

Facsimile Transmittal

To:	Fax: ( ) -
From:	Date: / /
Re: Patient Name	Pt. DOB:
CC:	Pages:

This fax has been sent to you with the consent of your patient to notify you that the patient named above received the following vaccination(s) at our pharmacy on the date that is listed below. Please make a note of this in the patient's chart and feel free to call at the number above with any questions.

Administration Date	Product	Dose	Comments

Medical Management of Vaccine Reactions in Adult Patients

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

Reaction	Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.

(continued on page 2)

Technical content reviewed by the Centers for Disease Control and Prevention, Nov. 2006.

www.immunize.org/catg.d/p3082.pdf • Item #P3082 (11/06)

(continued from page 1)

Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults

Supplies Needed

- ☐ Aqueous epinephrine 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen). If EpiPens are stocked, at least three adult EpiPens (0.30 mg) should be available.
- ☐ Diphenhydramine (Benadryl) injectable (50 mg/mL solution) and 25 mg or 50 mg capsules or tablets and syrup (12.5 mg/5 mL suspension)
- ☐ Syringes: 1–3 cc, 22–25g, 1", 1½", and 2" needles for epinephrine and diphenhydramine (Benadryl)
- ☐ Wristwatch with second hand
- ☐ Adult airways (small, medium, and large)
- ☐ Sphygmomanometer (adult and extra-large cuffs) and stethoscope
- ☐ Adult size pocket mask with one-way valve
- ☐ Alcohol swabs
- ☐ Tourniquet
- ☐ Tongue depressors
- ☐ Flashlight with extra batteries (for examination of the mouth and throat)
- ☐ Cell phone or access to an on-site phone

Signs and Symptoms of Anaphylactic Reaction

Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.

Treatment in Adults

a. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.

b. If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done by a second person, while the primary nurse assesses the airway, breathing, circulation, and level of consciousness of the patient.

c. Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01 mL/kg/dose (adult dose ranges from 0.3 mL to 0.5 mL, with maximum single dose of 0.5 mL).

d. In addition, for systemic anaphylaxis, administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1–2 mg/kg, up to 100 mg maximum single dose.

e. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.

f. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 10–20 minutes for up to 3 doses, depending on patient's response.

g. Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.

h. Notify the patient's primary care physician.

Sources: 1. American Academy of Pediatrics. Passive Immunization. In: Pickering LK, ed. *Red Book: 2006 Report of the Committee on Infectious Diseases.* 27th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2006:64–66.
2. American Pharmacists Association, Grabenstein, JD, *Pharmacy-Based Immunization Delivery,* 2002.
3. *Got Your Shots? A Providers Guide to Immunizations in Minnesota,* Second Edition, Minnesota Department of Health, 2001:80-82.

These standing orders for the medical management of vaccine reactions in adult patients shall remain in effect for patients of the _____ (*name of clinic*) until rescinded or until _____ (*date*).

_____ Medical Director's signature

_____ Effective date

Attachment 8

Emergency Response Materials For Training Sessions Conducted by the Department of Health Services on Healthcare Surge During Emergencies

State of California—Health and Human Services Agency
California Department of Health Services

SANDRA SHEWRY
Director

ARNOLD SCHWARZENEGGER
Governor

January 30, 2007

Dear Stakeholder:

I am writing to ask you to participate in an important initiative to help California's healthcare system prepare for a major disaster that could lead to a significantly increased demand for medical services.

Providing healthcare during a large-scale public health emergency presents significant challenges for healthcare facilities, licensed healthcare professionals, local health departments, and communities. During emergency events, healthcare systems must convert quickly from their existing patient capacity to "surge capacity" - a significant increase beyond usual capacity - to rapidly respond to the needs of affected individuals. The demands of a sustained or catastrophic emergency may prevent operating in accordance with existing healthcare standards. While California has healthcare standards for use during normal conditions, it is essential that California provide guidance with regard to the standards likely to be in effect during sustained emergency operations. This guidance should address professional standards of practice, facility operations, liability of hospitals and professionals, reimbursement of care, and standards for operations of alternate care sites. California is the first state to address surge planning in this manner.

The California Department of Health Services (CDHS) has contracted with PricewaterhouseCoopers, an international consulting firm, in an aggressive six-month project to address this challenge. The goal of this project is to provide the following:

- A standards and guidelines manual that addresses the existing statutes and regulations that currently govern the standards of care, and identifies those that may be flexed or waived during a declared emergency;
- Operational tools that will guide healthcare planners in the adoption and implementation of new temporary standards; and
- A training curriculum to support the planning and preparation for optimal surge response.

The success of this project depends on your involvement and that of other stakeholders to satisfactorily address issues and possible impediments to planning for the optimal surge response. We invite you to help address the complex issues of surge planning by actively participating in three Collaborative

Design Sessions. The Collaborative Design Sessions will be multi-day working sessions during which participants will identify the complex issues and gaps in current preparedness efforts with regard to the various aspects of surge planning. Resolution of gaps and issues identified at the Collaborative Design Sessions will take place in smaller workgroups that will be formed and convene after completion of the sessions.

1501 Capitol Avenue, Suite 6001, MS 0000 • P.O. Box 997413 • Sacramento, CA 95899-7413
(916) 440-7400 • (916) 440-7404 FAX • Internet address: www.dhs.ca.gov

The first Collaborative Design Session, focused on the operational aspects of surge planning – beds, facilities, labor, supplies, and equipment – will be a three-day session held from February 27 to March 1, 2007 in San Jose. The second Collaborative Design Session, focused on standards, guidelines and liability, will be a two-day session held on March 5 and 6, 2007 in Los Angeles. The third Collaborative Design Session, focused on reimbursement, will be a two-day session held on March 8 and 9, 2007 in Los Angeles. We anticipate approximately 100 participants for each Collaborative Design Session. If the number of participants registered for any session exceeds available space, we will implement a process of selection to determine the final attendees to the sessions. All interested stakeholders will be able to participate in the workgroups formed to resolve the issues and gaps identified in the Collaborative Design Sessions.

The enclosed materials provide a more detailed description of how CDHS and PricewaterhouseCoopers have organized this project and how you can participate. These materials are also available on our website at http://www.dhs.ca.gov/epo/surge

I actively encourage you and/or your organization to join us. You can indicate your interest in participating in one or more of the Collaborative Design Sessions, the workgroups, or being informed of progress throughout the project by registering on our website or by calling PricewaterhouseCoopers at (213) 217-3900. All registration will occur through this process.

On February 5 and February 8, 2007, we will hold one-hour teleconference sessions at 11 am to provide an overview of the project. The teleconference dial-in number for February 5 is (888) 801-1508, the access code is 861511. The dial-in number for February 8 is (888) 801-1513, the access code is 861512. If you have any questions about this letter, please feel free to contact Ted Selby in CDHS' Emergency Preparedness Office at (916) 650-6416.

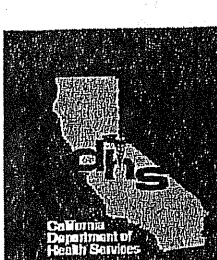
I thank you in advance and look forward to collaborating with you in this important project.

Sincerely,

Sandra Shewry

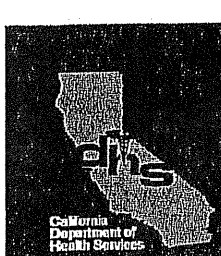
Sandra Shewry
Director

Enclosures



Development of Standards and Guidelines for Healthcare Surge during Emergencies

Stakeholder Orientation



Development of Standards and Guidelines for Healthcare Surge during Emergencies

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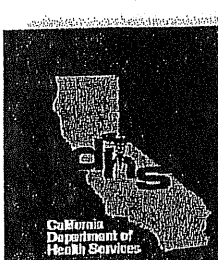


Development of Standards and Guidelines for Healthcare Surge during Emergencies

A. Background

Providing healthcare during a large scale public health emergency presents significant challenges for healthcare facilities, licensed healthcare professionals, and communities. During emergency events, healthcare systems must convert quickly from their existing patient capacity to "surge capacity" - a significant increase beyond usual capacity - to rapidly respond to the needs of affected individuals.

The demands of the emergency may prevent compliance with the existing healthcare standards. Just as California has healthcare standards for use with a normal operations, it is essential that California provide guidelines that identify the extent to which existing standards can be flexed or waived for healthcare delivery during emergencies. In order to assist healthcare providers to successfully plan for a healthcare surge, and as part of Governor Schwarzenegger's 2006 Surge Initiative, the California Department of Health Services (CDHS) has launched a project to address the issues of surge capacity during an emergency.

In February 2006, CDHS conducted the California Hospital Surge Capacity Survey, a statewide survey to assess healthcare surge capacity among Health Resources and Services Agency (HRSA) participants. The survey indicated that many California hospitals lack planning and resources needed to treat patients during emergencies that require significant or sustained surge and local health departments do not have the capacity to augment healthcare resources. Recognizing the importance and urgency of the problem, the State Budget Act for fiscal year 2006-2007 authorized CDHS to develop standards and guidelines to address the issues of surge capacity during an emergency.

Surge planning for the healthcare system is a substantial and complex challenge. In a time of significant disaster, a successful plan must predict and provide flexible arrangements to address capacity (volumes of patients) and capabilities (types of illnesses) that emerge above baseline requirements. The issues that need to be addressed are diverse and include:

- Standards of practice during an emergency
- Liability of hospitals and licensed healthcare professionals
- Reimbursement of care provided during an emergency
- Operating alternate care sites
- Surge capacity operating plans at individual hospitals

The deliverables for this project are intended to help every local healthcare provider, local health department, and community in California plan and put into operation a surge response to major disasters.

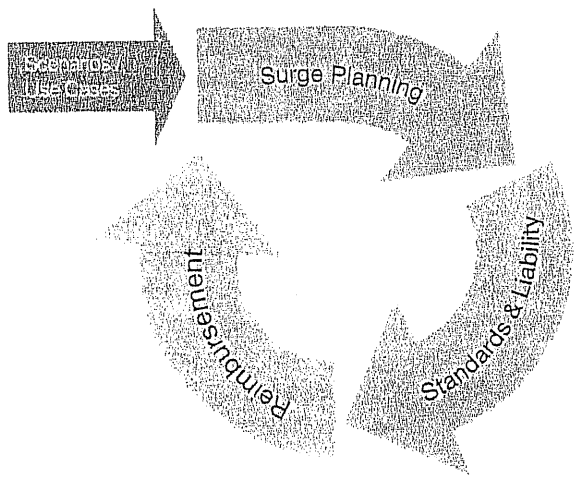
B. Approach

CDHS has contracted with PricewaterhouseCoopers LLP (PwC), an international consulting firm with a large US-based healthcare practice, to undertake this initiative in an aggressive six month period. PwC helped to create the post-Katrina blueprint for the recovery of the Louisiana healthcare system with resources that included physicians, nurses, healthcare planners, operating executives, standards and reimbursement experts, and experienced support staff.

The project approach is to assess the healthcare system's ability to surge using realistic examples of patients making their way through the delivery system during a significant disaster. This 'use case' methodology is a common way to evaluate experiences in complex and fragmented environments.

In consultation with subject matter experts, the project team will develop five patient profiles that will be used in three disaster scenarios that account for the vast majority of delivery challenges likely to be encountered in a surge environment during significant disasters. These 15 use cases will be used to identify planning gaps. In Collaborative Design Sessions, stakeholders will identify the challenges, barriers, and gaps in care faced by each of the patients in each disaster scenario. To effectively resolve these gaps, issues will be consolidated into three initiatives, each addressed in a separate Collaborative Design Session:

1. Surge planning (facilities including alternate care sites, equipment and supplies, and labor);
2. Standards and Liability; and
3. Reimbursement.



B. Approach (continued)

The project will begin by soliciting California stakeholders to participate in Collaborative Design Sessions. These intensively facilitated group activities use the collaboration of participants to surface and solve problems. For this project, stakeholders, based on their skill sets, will be asked to contribute their time to one of the three initiative areas. The Collaborative Design Sessions will address in sequence the three initiatives of Surge Planning, Standards and Liability, and Reimbursement. Each Collaborative Design Session will be two to three days in duration and is expected to include stakeholder participants with the relevant skills and experiences. The participants' task will be to analyze the 15 use cases for the purpose of identifying issues that could present impediments to the optimal surge environment. The issues that are identified in the first Collaborative Design Session (Surge Planning) will be included in the second Collaborative Design Session (Standards & Liability), and the combination of these issues will be included in the third Collaborative Design Session (Reimbursement). The overall goal of the three sessions will be to identify, assess, and prioritize as many issues as possible.

At the conclusion of the Collaborative Design Sessions, smaller workgroups will be formed to resolve issues identified in the Sessions. These workgroups will include the relevant stakeholders that participated in the original Collaborative Design Sessions, and additional stakeholders that are identified after the Collaborative Design Sessions. Over the subsequent few months, the workgroups will engage in issue resolution through interactive communication with their colleagues. As issues are resolved, they will be reviewed in by other workgroups to ensure relevance and completeness. The output from the workgroups will form the basis for the deliverables of this project.

C. What this Means for You

The standards and guidelines developed in this project will serve in the planning for delivery of care during an emergency surge environment where normal standards of care are diminished or non-existent. CDHS plans to disseminate the deliverables to local health departments, communities, healthcare facilities, individual licensed healthcare professionals, healthcare insurers and other key stakeholders for their use in planning for surge capacity.

Upon completion of this project, stakeholders will have access to:

- Standards and Guidelines Manual that will serve as a reference manual on existing statutory and regulatory requirements identifying what will be flexed or modified under different emergencies.
- Operational Tools that include forms, checklists and templates to facilitate and guide the adoption and implementation of statutory and regulatory requirements outlined in the Standards and Guidelines Manual.
- Training Curriculum outlining intended audience, means of delivery and frequency of training that will enable adherence to the policies and overall readiness of the healthcare delivery system.

D. Your Role as a Stakeholder

The best outcome of this project will only be accomplished with your help. From the outset, we envisioned that participation from a broad group of California healthcare stakeholders would be necessary to satisfactorily address the issues and impediments to planning for the optimal surge response. As a stakeholder, you have the opportunity to shape the issues and help to set the priority for their resolution.

Stakeholder organizations should identify personnel with the relevant experience to participate on this groundbreaking work, match relevant skills with initiatives. For example, on the Surge Planning initiative, participants who have responsibilities to moving patients and directly providing care would be appropriate. Likewise, risk managers, quality officers, and lawyers would be appropriate for the Standard and Liabilities initiative, and finally, reimbursement experts from payors and provider industries for Reimbursement.

The first Collaborative Design Session, focused on the operational aspects of surge planning – beds, facilities, labor, supplies, and equipment – will be a three-day session held from February 27 to March 1, 2007 in San Jose. The second Collaborative Design Session, focused on standards, guidelines and liability, will be a two-day session held on March 5 and 6, 2007 in Los Angeles. The third Collaborative Design Session, focused on reimbursement, will be a two-day session held on March 8 and 9, 2007 in Los Angeles.

A block of rooms has been set aside, at the rate indicated below, for each Collaborative Design Session, beginning the night before each session convenes. When making reservations please request the rate for the State of California Collaborative Design Session. Specific locations for the sessions are:

Surge Planning – February 27 – March 1, 2007
Holiday Inn San Jose
1740 North First St.
San Jose, CA 95112
(408) 793-3300
Room Rate: $115.00

D. Your Role as a Stakeholder (Continued)

Standards, Guidelines, and Liability – March 5 – 6, 2007
Westin Bonaventure
404 South Figueroa St.
Los Angeles, CA 90071
(213) 624-1000
Room Rate: $110.00

Reimbursement – March 8 – 9, 2007
Westin Bonaventure
404 South Figueroa St.
Los Angeles, CA 90071
(213) 624-1000
Room Rate: $110.00

We anticipate approximately 100 participants for each Collaborative Design Session. If the response for Collaborative Design Session participation is greater, we will implement a process of selection to determine the final attendees to the sessions. All interested stakeholders will be able to participate in the workgroups formed to resolve those issues and gaps identified in the Collaborative Design Sessions.

E. Getting Involved

Our goal is to create as many forums as possible for stakeholder participation. Thus, based on your availability and interest, you can participate in Collaborative Design Sessions, workgroups, or simply stay connected and informed via the following three channels:

- Internet: Stakeholder Web Portal, a website, will serve as the main communication vehicle and will allow you to (i) Obtain up-to-date project information and meeting schedules; (ii) Submit questions, ideas, and materials; (iii) Obtain copies of work documents; and (iv) Sign up for activities and email distribution lists. The portal can be accessed through the following URL: http://www.dhs.ca.gov/epo/surge

- Email: Stakeholders with questions, comments and concerns can send emails to **hcsurge@us.pwc.com**

- Phone: Stakeholders can call (213) 217-3900 to speak with a member of the project team. Stakeholders will be able to leave messages (accompanied with their name and phone number). A project team member will get back to the stakeholder as soon as possible.

We actively encourage you to get involved immediately. You can indicate your interest in participating in one or more of the Collaborative Design Session, resolving issues in workgroups, or being informed of progress throughout the project, by registering on our website or by calling PwC at (213) 217-3900. All registration will occur through the process outlined above.

On February 5 and February 8, 2007 we will be holding one-hour teleconference sessions at 11 am to provide an overview of the project. The teleconference dial-in number for February 5 is (888) 801-1508, the access code is 861511. The dial-in number for February 8 is (888) 801-1513, the access code is 861512.

Attachment 9

Materials on the California Pharmacy Intern Pharmacist Initiative

California Pharmacy IPPE/OSCE Initiative

The experiential component of the pharmacy curriculum provides a continuum of required and elective practice experiences that progress from basic (IPPEs) to more advanced (APPEs) activities under the supervision of qualified preceptors. Together, IPPEs and APPEs are designed to provide students with multiple opportunities to perform patient-centered care in a variety of real practice settings.

Background Situation

Recently, ACPE adopted new accreditation standards and guidelines (Standards 2007).

- Requirements for practice experiences are based upon amount of time spent:
  - IPPEs must be 5% of length of the curriculum; and
  - APPEs must be 25% of the length of the curriculum.
- Appendix C provides guidance on types of experiences appropriate for IPPEs and APPEs.
- The desired curricular outcomes (professional competencies) as a whole (i.e., for graduates) are described, but there is no delineation between IPPEs and APPEs in terms of the competencies that should be mastered in IPPEs prior to progressing to APPEs.

The California State Board of Pharmacy requires candidates for licensure to submit proof of 1500 hours of internship.

- Minimum of 900 hours must be completed in community or hospital practice settings.
- Up to 600 hours may be granted for other experiences substantially related to practice of pharmacy, which are generally provided by the schools for practice-related educational experiences.
- Students may apply for Intern licenses once registered in a school of pharmacy.

In the past, the State Board required candidates to submit two intern experience affidavits, one for community practice and one for institutional practice experiences. These affidavits listed specific practice objectives (competencies) that had to be signed off by licensed pharmacists. Currently, candidates for licensure only submit a 2-sentence affidavit, which they sign, stating that they have met the required internship requirements and have experience in both community and institutional pharmacy settings.

Relative to many other states, California schools of pharmacy admit a high percentage of educationally mature students. It is not uncommon for 90-95% or more of the entering classes at California schools to have earned a bachelors degree or higher. Many students have worked or volunteered in pharmacies prior to entering pharmacy school, with some having extensive experience as pharmacy technicians. While in school, the majority of California pharmacy students work as pharmacy interns and participate in professional organizations and co-curricular activities (e.g., health fairs, disease screenings, immunizations, smoking cessation programs, Medicare Part D outreach, indigent care clinics).

The Problems

The emphasis on the duration of experiences rather than the curricular outcomes resulting from them is problematic for many reasons. First, established schools are faced with adding course work to their (already packed) existing curricular, with no assurance that doing so would improve the quality of education for their graduates. If more time is to be spent in one aspect of the

curriculum, something will need to be removed elsewhere to avoid prolonging the time to graduation. This is especially problematic in California, where a high percentage of students already spend eight or more years in college prior to entering the profession.

Secondly, although individual schools have goals and learning objectives for IPPEs, there is no consistency or standard across schools regarding the types of practice activities offered or what students should learn or master. There is even less direction regarding appropriate activities for the State Board internship, which often results in pharmacy interns remaining in positions where they perform repetitive tasks at the expense of gaining experience with a broader array of more advanced professional responsibilities.

A third problem is that the new IPPE requirement does not provide sufficient flexibility in how schools will meet the standard. Students with extensive pharmacy technician experience should not be forced to repeat experiences that are of little educational value to them. Students working as interns in retail and hospital pharmacies may be able to achieve some of the foundational competencies through employment. Schools may wish to capture student participation in co-curricular activities such as disease screenings, Medicare outreach, and providing services to patients of indigent care clinics, which contribute to the development of professionalism and leadership skills among students. These types of activities promote a positive image of the profession and increase the public's awareness of the contributions that pharmacists make to improving health care outcomes.

Goals

The goals of this initiative are to:

1) Reach consensus on the basic foundational competencies that all pharmacy students in California should master during IPPEs (June 2007).
2) Train faculty members from each pharmacy school in California how to develop and administer an OSCE-based assessment (September 2007).
3) Develop a validated and standardized OSCE-based examination to assess achievement of the IPPE competencies (academic year 2007-08).
4) Develop a mechanism to assure replenishment of the OSCEs and exam security in the future (academic year 2007-08).
5) Petition ACPE to accept an OSCE-based assessment for IPPEs as evidence of compliance with Standards 10 and 14 in California (academic year 2007-08).

Proposal

1) The IPPE/OSCE Committee will identify and agree on the competencies that should be achieved by the end of IPPEs.
   a) Composition: 2-3 representatives from each school
   b) Invited participants: representatives from the state Board of Pharmacy, CPhA, CSHP, and other appropriate entities
   c) Meetings:
      a. January 23, 2007, 10:00 am – 3:00 pm, San Francisco (UCSF)
      b. February 27, 2007, 10:00 am – 3:00 pm, Los Angeles (USC)
      c. March 27, 2007, 10:00 am – 3:00 pm, San Francisco (UCSF)
   d) Decisions: Each participating school would have one vote when making decisions.

e) Background materials: The State Board of Pharmacy's community and institutional internship experience affidavits, NAPLEX Blueprint 2005

2) The committee will sponsor two 1.5 day statewide OSCE conferences to train faculty teams from each school on how to develop and administer OSCEs. The goal is to produce a bank of 40+ OSCE stations for the IPPE assessment. Zubin Austin (University of Toronto) has agreed to lead the conferences.
   a) First conference (San Francisco, June 5-6, 2007). Topics will include an overview of OSCEs (primer), developing the exam blueprint, defining stations, and developing the initial cases.
   b) Interlude: faculty teams will develop additional cases/stations (5-7 per school).
   c) Second conference (San Diego, week of August 20, 2007). Topics will include review and validation of the additional cases/stations, setting standards, determining station set up and training requirements, determining data analysis (cut scores), determining security procedures and establishing a mechanism to replenish cases in the future.

3) The committee will pursue external funding to offset the expenses associated with committee meetings and the OSCE conference(s). If not successful, schools will share the costs equally.

4) Schools will select 7-9 OSCE cases/stations from the database for each assessment, based upon individual needs and preferences. Exams may be offered at different times, but all schools agree to follow the established procedures and security measures.

5) Appoint representative(s) from each school to meet on an annual basis to share experiences with the exams and generate new cases/stations to replenish the database.

California Pharmacy IPPE-OSCE Initiative Meeting
Jan. 23, 2007, 10AM – 3PM
UCSF Faculty Alumni House

Attendees:
Barbara Sauer, UCSF (Co-Chair)

Kathy Besinque, USC (Co-Chair)
Eric Boyce, UOP (Co-Chair)

Sarang Aranke, Target
Elizabeth Boyd, UCSF
James Colbert, UCSD
Robin Corelli, UCSF
William Gong, USC
Steven Gray, Kaiser
Gamal Hussein, Loma Linda University
Paul Lofholm, CPhA
Susan Ravnan, UOP
Debra Sasaki-Hill, Touro University
Sam Shimomura, Western University
Anne Sodergren, CA State Board of Pharmacy
Rick Sylvies, Western University
Reza Taheri, Loma Linda University
Dianne Tobias, Tobias Consulting Services
Dave Williams, Safeway
Annie Wong-Beringer, USC
Sharon Youmans, UCSF
Keith Yoshizuka, Touro University

Unable to Attend:
Sian Carr-Lopez, UOP
Jeff Goad, USC
Kelli Haase, CSHP
Virginia Herold, CA State Board of Pharmacy
Robert Ignoffo, CSHP
Marilyn Shreve, Astra Zeneca

Action Items Before Next Meeting

1. Review draft minutes and submit any corrections to Barbara.
2. **Between now and the next meeting, each group should work on it's own statements to complete the list.** Are there any gaps, overlaps or inconsistencies? Are the statements prioritized?
3. Edit the statements to be consistent in language and written in **measurable** terms.
4. Send your revisions to Barbara **by February 23.**

Date/Location/Time of Next Meeting: Tuesday, February 23, 2007 at USC, 10AM-3PM

1. Welcome and Introductions

Mary Anne Koda-Kimble, dean of the UCSF School of Pharmacy welcomed those in attendance. She presented an overview of how the initiative got started and the widespread support that it was receiving. Following her remarks, members of the group introduced each other, describing their positions and reasons for participation.

2. Background and Goals

Barbara Sauer presented an overview of the project goals and process planned to accomplish these goals. She described experiential education in terms of what the schools supervise (IPPEs through APPEs, now 30% of the curriculum) and what the State Board oversees (Internship, 1500 hours). She concluded with a review of the agenda for this meeting and some things to keep in mind when defining the IPPE-APPE interface. Mary Anne suggested adding another goal, a scholarly evaluation of the project.

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Jan. 23, 2007, 10AM – 3PM
UCSF Faculty Alumni House

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Attachment 10

Fact Sheet on the New Test Administration Company for the CPJE

New CPJE Testing Company Selected

The Department of Consumer Affairs has selected a new company to administer professional licensing exams. The Board of Pharmacy will use this new company to give the California Pharmacist Jurisprudence Examination (CPJE) beginning June 1, 2007.

Please review the following information - - it will affect how you will take the CPJE in the future.

You will need to include this completed form when submitting your pharmacist licensure examination.

****

The Board of Pharmacy (board) currently uses Thomson Prometric (Thomson) to administer the California Pharmacist Jurisprudence Exam (CPJE). This will not in any way affect the NAPLEX.

Effective June 1, 2007: Psychological Services, LLC. (PSI) will provide testing services for the CPJE. (Thomson will no longer be available to test pharmacist candidates for the CPJE).

While the board does not anticipate that this change in companies will affect candidates and their ability to take the CPJE, there is always the possibility of a delay in contract implementation that could cause a delay in the candidates' ability to take the CPJE. The board is taking every measure to minimize the effect on the candidates. Candidates should also be aware that the board also anticipates a quality assurance assessment to begin on June 1, 2007 (this is when exam scores are held until the review is complete).

As information becomes available about how to schedule the CPJE with PSI, the board will notify candidates, post information on the board's Web site and issue subscriber alerts.

The board will do everything in its power to make this transition as seamless as possible for the candidates.

BASIC INFORMATION:

- <u>If you want to take the CPJE on or before May 31, 2007</u>:
  Make certain that once you are made eligible by the board to take the CPJE, you schedule your exam time with Thompson (and that you schedule the exam before May 31, 2007). If you are currently eligible but have not yet made your appointment

to take the CPJE, please schedule it now. You will need to take it on or before May 31, 2007, if you wish to test at a Thomson test center.

- If you want to take the CPJE on or after June 1, 2007:
  Once the board receives information about how to make appointments with PSI, the board will advise you. However, recognize that:
  - -- Unforeseen implementation issues may delay your ability to take the CPJE until the contract matters are resolved with PSI
  - -- PSI may have higher test-taking fees or have entirely different testing locations
  - -- The board will likely institute a quality assurance review with the new exam testing company, which will delay the release of your results until approximately 400 individuals take the exam

The Department of Consumer Affairs advises candidates eligible on and after May 1, 2007, that you may need to wait for PSI to take over testing duties for the CPJE. Candidates will be required to select one of the following to take the CPJE.

Please complete the following and include with your application and select one of the options. If you do not select an option, you will be assigned Option #1.

Last Name	First Name	Middle Name	Date of Birth
Email Address			

Check One	Option Descriptions	
	Option #1:	I wish to take the CPJE with PSI after June 1, 2007. I recognize that I may take the NAPLEX, and the board will allow me one year from the date the CPJE is available from PSI to take the CPJE.
	Option #2:	I wish to be made eligible to take the CPJE through Thomson before or up to May 1, 2007, and will take the CPJE with Thomson before to May 31, 2007.

Attachment A

Meeting Summary of the Licensing Committee Meeting of March 7, 2007

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Licensing Committee
Summary of the Meeting of March 7, 2007

Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

Present: Ruth Conroy, PharmD, Chair and Board Member
Clarence Hiura, PharmD, Board Member
Susan Ravnan, PharmD, Board Member
Robert Graul, RPh, Board Member

Virginia Herold, Executive Officer
Anne Sodergren, Legislation Coordinator
Judi Nurse, PharmD, Supervising Inspector

Chairperson Conroy called the meeting to order at 10 a.m.

Proposed Regulation Requirements for Compounding by Pharmacies

At the January 2007 Board Meeting, the board moved to regulation hearing proposed regulations for pharmacies that compound medication, providing patient protections when they receive medication compounded by a pharmacy. The draft regulations were developed during 2004 while the board was convening its Work Group on Compounding with stakeholders and other regulatory agencies.

At the January Board Meeting, noting that some individuals may wish to comment on the regulations before they are noticed, the board asked that those individuals with comments to provide these comments to the Licensing Committee by the end of February.

Comments were provided to Licensing Committee by CPhA, NACDS and Dan Wills. The comments of CPhA and Dan Wills were blended into a draft manuscript for committee review during the meeting. The comments of NACDs were received too late to incorporate into this manuscript.

Discussion during the meeting resulted in the staff being asked to work on the comments submitted and to return a draft to the committee for additional review.

The committee also discussed new legislation introduced at the federal level by Senator Kennedy to prohibit pharmacies from performing compounding.

Request to Add the ExCPT Exam as an Additional Qualifying Method to Become a Pharmacy Technician

Ms. Herold updated the committee on the status of the review of the ExCPT exam, which has been developed by the Institute for the Advancement of Community Pharmacy Technicians (ICPT) as a means to assess the knowledge of applicants for a pharmacy technician registration

At the September committee meeting, staff was directed to develop a plan to review the ExCPT exam to determine if it meets the requirements of the California Business and Professions Code section 139 regarding a valid examination. Ms. Herold explained that she had hoped to use psychometric staff of the Office of Examination Resources in the Department of Consumer Affairs to perform this review. This office provides examination and psychometric services to professional and vocational licensing boards within the department. However, the office is without a PhD psychometric expert who could assist the board in performing this review. This position has been vacant since September and the department is having a difficult time with recruitment.

Discussions are currently underway between the board and departmental staff on establishing an alternative method to initiate a review of the ExCPT exam, as well as the PTCB.

The committee and audience discussed the need for evaluation of the training of technicians. Dr. Ravnan stated that she believes that there needs to be more than just an examination component for pharmacy technicians – practical training is also important. She stated that the forthcoming SCR 49 Medication Errors Report will include a need for well-trained technicians.

A comment was made that both CPhA and CSHP are taking a look at the performance required of technicians, and whether additional qualifications are needed. Other individuals suggested that two types of registration for technicians may be needed: one standard for community pharmacy technicians and another for hospital pharmacy technicians.

There was no action on this agenda item.

Proposal from the California Schools of Pharmacy to Identify Professional Competencies that Should be Obtained by the End of the Basic Internship Experience

The Board of Pharmacy voted to join in a project initiated by California's schools of pharmacy, who are working together with other stakeholders to evaluate the components of ACPE approved intern experience at both the basic (IPPE) and advanced (APPE) levels. The project is called the California Pharmacy IPPE/OSCE Initiative. The goal is to develop an alternative component to assessing intern experience.

The California pharmacy schools are collaborating on this new initiative to determine and assess the competencies that students should achieve by the end of their introductory pharmacy practice experiences (IPPEs) prior to starting their advanced pharmacy practice experiences (APPEs). This initiative is in response to new ACPE accreditation standards that spell out how much time students must spend in IPPEs and APPEs rather than what they should learn (outcomes). The ACPE believes that there should be 300 hours of this basic experience.

Two day-long meetings have taken place so far – January 26 and February 28.

Dr. Ravnan, who is the board's appointee to the committee stated that work groups have been formed to develop skills that interns should learn as part of the basic internship training.

Following identification of these skills, the schools will attempt to develop a performance-based exam (i.e., objective structured clinical exam, OSCE) to assess student achievement of these competencies.

The timeline of the schools is to aim for incorporation of the standards during academic year 2007-08.

Request by Pacific University of Oregon to Receive Board Recognition for Purposes of Issuing California Pharmacist Intern Licenses

Dr. Conroy stated that Pacific University School of Pharmacy has requested that the Board of Pharmacy recognize its school of pharmacy for purposes of approving intern applications.

Current regulation, 16 CCR section 1719, states that a "recognized school of pharmacy" means a school accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education (ACPE).

Pacific University School of Pharmacy is in precandidate status, but is proceeding toward eligibility to candidate accreditation status.

According to the ACPE, its Board of Directors will make a decision on the status of Pacific University School of Pharmacy in June 2007 with information available to the general public in mid-July. A program that achieves candidate accreditation status can remain in this status from 2-4 years before advancing to full accreditation status. Historically, pharmacy programs that advance to candidate status do achieve full accreditation status, but ACPE cannot guarantee that any particular school will do so in the future.

After discussion, the committee agreed to recommend approval of this request.

Motion: Ravan/Hiura: Recommend approval of Pacific University School of Pharmacy for purposes of issuing intern pharmacist licenses to its students.
3-0

Update: Disaster Response for California Pharmacy/Health Care Surge Project

At the October Board Meeting, the board amended and approved a general policy statement that outlines its expectations for how disaster response in California may proceed. This policy statement is on the board's Web site and was published in the January 2007 *The Script*.

Ms. Herold noted that at the end of February and the first week in March, the state is hosting a conference for state agencies on disaster preparedness. Several inspectors from the board are attending the conference. The schedule for these seven days of training is:

February 27-March 1: Surge Response
March 5-6: Standards and Liability
March 8-9: Reimbursement

Chairperson Conroy directed the committee to background materials on this training in the committee's packet. Inspector Ralph Orlandella attended the three-day "Surge Response" session, and Chairperson Conroy stated she was able to attend the March 1 session.

Inspector Orlandella provided information about the training which is being coordinated under contract by Price Waterhouse. He indicated that the general feeling of some of those 0coordinating the training that since there is a pharmacist shortage, there may not be sufficient pharmacists available to respond to emergencies, which was very frustrating to Dr. Orlandella.

The information collected during these sessions will be used by the Department of Health Services to develop emergency response plan for immediate response to disasters. Once developed, this information will be shared with the committee and board.

Proposals for Legislative Amendments

Chairperson Conroy noted that staff has submitted two proposals for legislative changes to existing California requirements.

1. ***Amend Sections 4200-4200.3***

   Staff suggests that the statutory reference for what the board calls the California Pharmacist Jurisprudence Examination (CPJE) be changed to more accurately reflect the statutorily established breath of the exam to <u>The California Pharmacist-Patient Communication and Jurisprudence Examination</u>.

   The committee supported this recommendation, but thought that perhaps a better name could be established.

   Motion: Hiura/Graul: Move proposal to board recommending adoption
   3-0

2. ***Amend section 4052.(a)(9) to allow pharmacists to administer immunizations pursuant to the National Protocol for Vaccinations***

   Jeff Goad, PharmD, a professor at USC, provided information to the committee about a proposal to establish a statewide protocol under which pharmacists could administer immunizations if using the CDC's National Protocol for Vaccinations. If such a statutory modification is made, the board would need to develop regulations with specific protocols in them.

   Dr. Goad stated that in 44 states, pharmacists can administer immunizations. He distributed information about pharmacy immunization protocols for a number of vaccines.

   Discussion was very supportive.

   Motion: Graul:Hiura: Recommend that the board approve the establishment of a state protocol under which pharmacists can administer vaccines.

<u>Request to Accept the Certification Examination of the Commission for Certification in Geriatric Pharmacy for Continuing Education Credit for Pharmacists</u>

The committee was advised that the Commission for Certification in Geriatric Pharmacy will attend the April Board Meeting to request that the board award continuing education credits to those pharmacists who past the commission's certification examination to become a Certified Geriatric Pharmacist. According to this association, there are 1,300 certified geriatric pharmacists in the US, Canada, Australia and other counties. To become certified, the individual must pass a 3-hour, 150-question examination covering three areas: patient specific, disease specific, and population specific activities. Two states, Ohio and Washington, do award CE units for passing this examination.

The committee asked for the commission to appear so the board could learn more about the examination and qualifying process.

Strategic Plan Update for 2007/08

Chairperson Conroy asked the committee if they had modifications to suggest to the committee's strategic plan for 2007-08. She noted that a major revision was made in the plan last year, but each year in the spring, the board revises its plan to keep it current.

No changes were suggested to the committee's strategic objectives.

NABP Accredits Suppliers of Durable Medical Equipment

Chairperson Conroy noted that for informational purposes only: that the National Association of Boards of Pharmacy has been approved by the Centers for Medicare and Medicaid Services to become an accrediting organization for suppliers of durable medical equipment, prosthetics, orthotics and supplies.

According to the NABP, the goal of the program is to ensure that Medicare beneficiaries receive the appropriate products, services, a patient care associated with these items.

Competency Committee Report

The Department of Consumer Affairs awarded the test administration contract for departmental professional and vocational licensing exams (which is what the board uses to administer the CPJE) to Psychological Services LLC (PSI) on February 28, 2007. This is a new company.

While there was a protest filed with the DCA's Office of Examination Resources, the contract was nevertheless awarded since the new agreement contained language to move forward with a winning vendor even if there should be a protest.

Ms. Herold stated that board staff attended an information-sharing meeting on contract implementation on March 1, 2007. Board staff will be working the DCA on the transition from using the current vendor (Thompson Prometric) to the new vendor, PSI.

Given that there will be a new vendor on June 1, there will be transition issues, and the timing is bad for June pharmacy school graduates. The board is now developing materials to educate applicants about the new testing company. However, the board does not have any information about how to apply to take the exam from the new vendor, how much it will cost and what testing locations exist.

Ms. Herold also stated that staff is working with California pharmacy schools to advise them of the new vendor and aid them in getting their graduates into the examination at Thompson Prometric sites if the students graduate prior to mid-May.

An informational fact sheet is being prepared, and all CPJE-eligible candidates are being notified they need to schedule and take the examination with Thompson Prometric before June 1.

Adjournment

There being no additional business, Chairperson Conroy adjourned the meeting at 1 p.m.

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

Objective 2.1	Issue licenses within 3 working days of a completed application by June 30, 2011.
Measure:	Percentage of licenses issued within 3 work days.
Tasks:	1. Review 100 percent of all applications within 7 work days of receipt.

	Apps. Received:				Average Days to Process:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	364	280*	172**	N	9.27	3	3	N
Pharmacist (initial licensing)	532	327*	89**	N	3.5	5	20	N
Pharmacy Intern	559	576*	159**	N	30	30	30	N
Pharmacy Technician	1650	1506*	1025**	N	16	16	16	N
Pharmacies	120	92	139	N	10	12	27	N
Non-Resident Pharmacy	7	19	22	N	30	16	44	N
Wholesaler	7	20	17	N	30	30	29	N
Veterinary Drug Retailers	0	0	1	N	0	0	0	N
Designated Representative	93	102	75	N	4	15	10	N
Out-of-state distributors	31	29	19	N	30	30	27	N
Clinics	23	14	14	N	15	13	15	N
Hypodermic Needle & Syringe Distributors	0	4	3	N	10	15	14	N
Sterile Compounding	10	5	4	N	4	7	5	N

**Denotes only October and November 2006 information that was available at time of report development.

*Denotes updated data to include September 2006 information.

2. Process 100 percent of all deficiency documents within 5 work days of receipt.

	Average Days to process deficiency:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	10	10	10	N
Pharmacist (initial licensing)	10	10	10	N
Pharmacy Intern	10	10	10	N
Pharmacy Technician	4	5	7	N
Pharmacies	15	2	4	N
Non-Resident Pharmacy	12	15	5	N
Wholesaler	11	10	12	N
Veterinary Drug Retailers	0	10	2	N
Designated Representative	10	10	5	N
Out-of-state distributors	10	10	12	N
Clinics	10	7	2	N
Hypodermic Needle & Syringe	0	6	9	N

3. Make a licensing decision within 3 work days after all deficiencies are corrected.

	Average Days to Determine to Deny/Issue License:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	1	1	3	N
Pharmacist (initial licensing)	1	1	3	N
Pharmacy Intern	1	1	3	N
Pharmacy Technician	3	3	3	N
Pharmacies	5	4	3	N
Non-Resident Pharmacy	3	1	5	N
Wholesaler	3	5	5	N
Veterinary Drug Retailers	0	2	1	N
Designated Representative	1	2	2	N
Out-of-state distributors	3	5	5	N
Clinics	1	2	1	N
Hypodermic Needle & Syringe	0	1	1	N

4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.

	Licenses Issued:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	532	375	185	N
Pharmacy Intern	524	587	187	N
Pharmacy Technician	2189	1516	1296	N
Pharmacies	95	128	141	N
Non-Resident Pharmacy	5	11	9	N
Wholesaler	3	11	16	N
Veterinary Drug Retailers	0	1	1	N
Designated Representative	42	91	124	N
Out-of-state distributors	9	19	27	N
Clinics	27	13	13	N
Hypodermic Needle & Syringe	0	10	6	N
Sterile Compounding	18	13	5	N

5. Withdrawn licenses to applicants not meeting board requirements.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	0	11	unavail.	N
Pharmacies	2	4	1	N
Non-Resident Pharmacy	2	13	1	N
Clinics	0	22	0	N
Sterile Compounding	0	0	0	N
Designated Representative	0	0	4	N
Hypodermic Needle & Syringe	0	1	0	N
Out-of-state distributors	0	14	0	N
Wholesaler	2	16	4	N

6. Deny applications to those who do not meet California standards.

Objective 2.2 Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2011.

Measure: Percentage of cashiered application and renewal fees within 2 working days.

Tasks:

1. Cashier application fees.
   - *1st Qtr 06/07:* *The average processing time for processing new application fees is 2-3 working days.*
   - *2nd Qtr 06/07:* *The average processing time for processing new application fees is 2-3 working days.*
   - *3rd Qtr 06/07:* *The average processing time for processing new application fees is 3 working days.*
2. Cashier renewal fees.
   - *1st Qtr 06/07:* *The average processing time for cashiering is 2-3 working days.*
   - *2nd Qtr 06/07:* *The average processing time for cashiering is 2-3 working days.*
   - *3rd Qtr 06/07:* *The average processing time for cashiering is 2-3 working days.*
3. Secure online renewal of licenses.
   - *1st Qtr 06/07:* *Board meets with programmers to initiate parameters for board licensing programs to convert to DCA Applicant Tracking Program.*
   - *Jan. 2007:* *Board converts all application programs to DCA's Applicant Tracking Program. See Objective 2.4, Task 7 below.*

Objective 2.3	Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2011.
Measure:	Percentage of licensing records changes within 5 working days.
Tasks:	1. Make address and name changes. *1st Qtr 06/07:* *Processed 1,832 address changes.* *2nd Qtr 06/07:* *Processed 1,322 address changes.* *3rd Qtr 06/07:* *Processed 1,613 address changes.* 2. Process discontinuance of businesses forms and related components. *1st Qtr 06/07:* *Processed 41 discontinuance-of-business forms. Processing time is 46 days.* *2nd Qtr 06/07:* *Processed 0 discontinuance-of-business forms.* *3rd Qtr 06/07:* *Processed 72 discontinuance-of-business forms. Processing time is 30 days.* 3. Process changes in pharmacist-in-charge and designated representative-in-charge. *1st Qtr 06/07:* *Processed 247 pharmacist-in-charge changes. Average processing time is 30 days. Processed 0 designated representative-in-charge changes.* *2nd Qtr 06/07:* *Processed 382 pharmacist-in-charge changes. Average processing time is 30 days. Processed 5 designated representative-in-charge changes. Average processing time is 10 days.* *3rd Qtr 06/07:* *Processed 358 pharmacist-in-charge changes. Average processing time is 30 days. Processed 0 designated representative-in-charge changes.* 4. Process off-site storage applications. *1st Qtr 06/07:* *Processed and approved 42 off-site storage applications. Average processing time is 30 days.* 5. Transfer of intern hours to other states. *1st Qtr 06/07:* *Processed 76 applications. Average processing time is 30 days.* *2nd Qtr 06/07:* *Processed 45 applications. Average processing time is 30 days.*

Objective 2.4	Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Measure:	Number of implemented changes.
Tasks:	1. Determine why 26 states do not allow the use of a CA license as the basis for transfer a pharmacist license to that state. *Jan. 2007:* *Survey of some states indicate misunderstanding of why California cannot accept NAPLEX scores earned before January 1, 2004. Educational efforts, on a state by state basis, initiated.* 2. Work with the University of California to evaluate the drug distribution system of its clinics and their appropriate licensure. 3. Work with the Department of Corrections on the licensure of pharmacies in prisons. 4. Work with local and state officials on emergency preparedness and planning for pandemic and disasters. Planning to include the storage and distribution of drugs to assure patient access and safety. *Sept. 2006:* *Committee hears presentation by DHS on emergency preparedness.* *Oct. 2006:* *Presentation by Orange County and LA emergency response staff at NABP District 7 & 8 meeting. Board meeting has presentation by DHS and board develops policy statement for licensees in responding to declared emergencies.* *Jan. 2007:* *Board publishes disaster response policy statement.* *Feb. & March 2007:* *Board attends seven-day DHS-hosted training session on surge emergency response as part of the state's disaster response.* 5. Evaluate the need to issue a provisional license to pharmacy technician trainees. 6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians. *Sept. 2006:* *Committee hears presentation on ExCPT exam approved for certification of technicians by five states. Committee directs staff to evaluate exam for possible use in California.* *Dec. 2006:* *DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.* *March 2007:* *DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.* 7. Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008. *July 2006:* *Board executive officer becomes executive sponsor of program.* *Nov. 2006:* *Board completes system identification of parameters for each licensing program.* *Dec. 2006-Jan. 2007:* *Preparatory work and pilots completed; Board Staff initiates transfer to ATS system as sole platform for applicant tracking for all licensing programs.* *March 2007:* *Work on securing vendors for I-Licensing continues. Staff changes at DCA may delay implementation.*